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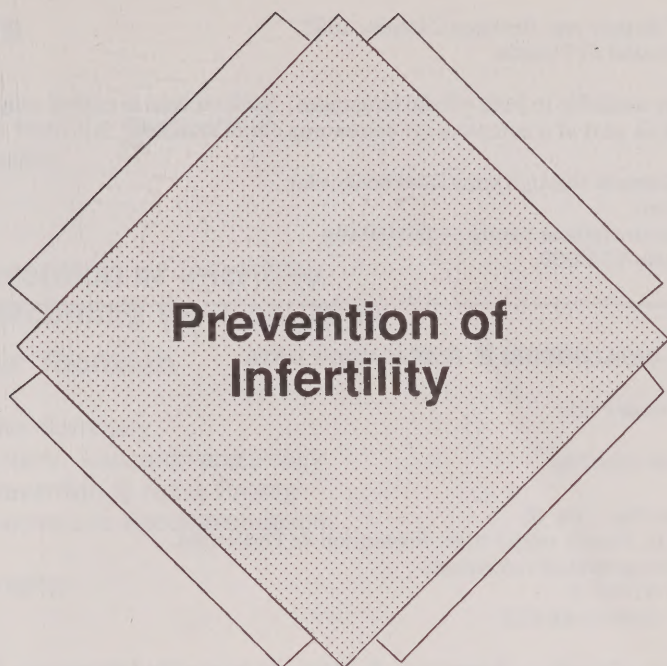
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# PREVENTION OF INFERTILITY

Research Studies of the  
Royal Commission on  
New Reproductive Technologies





# **Prevention of Infertility**

**Volume 8 of the  
Research Studies**

**Royal Commission on  
New Reproductive Technologies**



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## Preface from the Chairperson



As Canadians living in the last decade of the twentieth century, we face unprecedented choices about procreation. Our responses to those choices — as individuals and as a society — say much about what we value and what our priorities are. Some technologies, such as those for assisted reproduction, are unlikely to become a common means of having a family — although the number of children born as a result of these techniques is greater than the number of infants placed for adoption in Canada. Others, such as ultrasound during pregnancy, are already generally accepted, and half of all pregnant women aged 35 and over undergo prenatal diagnostic procedures. Still other technologies, such as fetal tissue research, have little to do with reproduction as such, but may be of benefit to people suffering from diseases such as Parkinson's; they raise important ethical issues in the use and handling of reproductive tissues.

It is clear that opportunities for technological intervention raise issues that affect all of society; in addition, access to the technologies depends on the existence of public structures and policies to provide them. The values and priorities of society, as expressed through its institutions, laws, and funding arrangements, will affect individual options and choices.

As Canadians became more aware of these technologies throughout the 1980s, there was a growing awareness that there was an unacceptably large gap between the rapid pace of technological change and the policy development needed to guide decisions about whether and how to use such powerful technologies. There was also a realization of how little reliable information was available to make the needed policy decisions. In addition, many of the attitudes and assumptions underlying the way in which technologies were being developed and made available did not reflect the profound changes that have been transforming Canada in recent decades. Individual cases were being dealt with in isolation, and often in the absence of informed social consensus. At the same time, Canadians were looking

more critically at the role of science and technology in their lives in general, becoming more aware of their limited capacity to solve society's problems.

These concerns came together in the creation of the Royal Commission on New Reproductive Technologies. The Commission was established by the federal government in October 1989, with a wide-ranging and complex mandate. It is important to understand that the Commission was asked to consider the technologies' impact not only on society, but also on specific groups in society, particularly women and children. It was asked to consider not only the technologies' scientific and medical aspects, but also their ethical, legal, social, economic, and health implications. Its mandate was extensive, as it was directed to examine not only current developments in the area of new reproductive technologies, but also potential ones; not only techniques related to assisted conception, but also those of prenatal diagnosis; not only the condition of infertility, but also its causes and prevention; not only applications of technology, but also research, particularly embryo and fetal tissue research.

The appointment of a Royal Commission provided an opportunity to collect much-needed information, to foster public awareness and public debate, and to provide a principled framework for Canadian public policy on the use or restriction of these technologies.

The Commission set three broad goals for its work: to provide direction for public policy by making sound, practical, and principled recommendations; to leave a legacy of increased knowledge to benefit Canadian and international experience with new reproductive technologies; and to enhance public awareness and understanding of the issues surrounding new reproductive technologies to facilitate public participation in determining the future of the technologies and their place in Canadian society.

To fulfil these goals, the Commission held extensive public consultations, including private sessions for people with personal experiences of the technologies that they did not want to discuss in a public forum, and it developed an interdisciplinary research program to ensure that its recommendations would be informed by rigorous and wide-ranging research. In fact, the Commission published some of that research in advance of the Final Report to assist those working in the field of reproductive health and new reproductive technologies and to help inform the public.

The results of the research program are presented in these volumes. In all, the Commission developed and gathered an enormous body of information and analysis on which to base its recommendations, much of it available in Canada for the first time. This solid base of research findings helped to clarify the issues and produce practical and useful recommendations based on reliable data about the reality of the situation, not on speculation.

The Commission sought the involvement of the most qualified researchers to help develop its research projects. In total, more than 300



scholars and academics representing more than 70 disciplines — including the social sciences, humanities, medicine, genetics, life sciences, law, ethics, philosophy, and theology — at some 21 Canadian universities and 13 hospitals, clinics, and other institutions were involved in the research program.

The Commission was committed to a research process with high standards and a protocol that included internal and external peer review for content and methodology, first at the design stage and later at the report stage. Authors were asked to respond to these reviews, and the process resulted in the achievement of a high standard of work. The protocol was completed before the publication of the studies in this series of research volumes. Researchers using human subjects were required to comply with appropriate ethical review standards.

These volumes of research studies reflect the Commission's wide mandate. We believe the findings and analysis contained in these volumes will be useful for many people, both in this country and elsewhere.

Along with the other Commissioners, I would like to take this opportunity to extend my appreciation and thanks to the researchers and external reviewers who have given tremendous amounts of time and thought to the Commission. I would also like to acknowledge the entire Commission staff for their hard work, dedication, and commitment over the life of the Commission. Finally, I would like to thank the more than 40 000 Canadians who were involved in the many facets of the Commission's work. Their contribution has been invaluable.

A handwritten signature in dark ink, reading "Patricia A. Baird". The script is cursive and elegant, with the first letters of each word being capitalized and prominent.

Patricia Baird, M.D., C.M., FRCPC, F.C.C.M.G.



## Introduction



Preventing infertility before it occurs is less dramatic and personal than assisting an infertile couple to have a child. Although prevention programs do benefit particular individuals, they are directed at groups or populations; they are concerned not with dramatic and identifiable outcomes for particular individuals, but with avoiding the need for drama for people whose identity is never known. Although, for the foreseeable future, a significant level of infertility cannot be prevented, it is likely that many of the women and men currently seeking infertility treatment would not have needed such treatment if there had been adequate and timely programs aimed at the prevention of infertility.

Volume 6, on the prevalence of infertility, showed that 7 percent of Canadian couples of reproductive age are unable to have a pregnancy even after two years of trying. But while they may share the same problem — the inability to have a child — the ways by which they have arrived at this situation differ from couple to couple. We identified many different risk factors for infertility in Volume 7, and prevention strategies must be targeted with these differing causes or factors in mind.

Some risk factors, for instance, such as sexually transmitted diseases (STDs) and smoking, are already being addressed through prevention programs, but more attention needs to be drawn to the risk these factors pose to fertility in particular. Others, such as environmental and workplace hazards, can be identified and controlled through appropriate measures, thus reducing exposure to them, but, as we outline in the Commission's Final Report as well as in these volumes, much more research is needed in this area. Risk factors such as those related to weight, eating disorders, and exercise, can be dealt with through counselling and related responses. Even factors that are not as amenable to personal action, such as mild endometriosis and delayed childbearing, at least can be addressed through

the dissemination of timely information about the implications of these factors for fertility.

It is clear from the papers that appear in this volume, and from the range of responses mentioned above, that the prevention of infertility is a complex area. There is a great deal that needs to be learned about all aspects of prevention, both as a health care initiative and as a dimension of social policy. One of the recurrent themes running through the volume is the need for reliable outcome information after prevention initiatives upon which to base program design and policy decisions. These papers also show, however, that prevention is a viable response and that there is clear evidence of the cost both to society and to individuals of *not* acting to prevent infertility wherever possible.

Finally, taken together, these papers clearly demonstrate that prevention of infertility cannot be achieved by the health care system alone, but that the schools, the community, and the workplace all have necessary roles to play.

## The Studies

There are very real challenges involved in making prevention of infertility a public policy priority, and Alistair Thomson identifies 10 “obstacles to putting prevention on the political agenda.” Among the obstacles he identifies are ones that we believe the Commission has helped to remove — for instance, the Commission’s research has established the prevalence of infertility; it has identified who should be responsible for various aspects of prevention; and it has provided some data with regard to the effectiveness of prevention. Dr. Thomson also suggests various strategies for overcoming the obstacles he identifies, including increased efforts to prevent the spread of STDs among adolescents, ongoing monitoring of the prevalence of infertility among Canadians, and federally funded research to assess the cost-effectiveness of prevention.

Lynn McIntyre examines the obstacles involved in evaluating programs aimed at the prevention of infertility linked to STDs. She finds that efforts to identify effective prevention programs are hampered by the limits of basic science knowledge, including a lack of knowledge about preventable causes of infertility; by methodological limitations, including problems in measuring outcomes in a meaningful way; and by political constraints, including the fact that infertility prevention has not been a specific focus of STD prevention programs and there has been a lack of political will to make it a focus.

Not having effective prevention is costly, as Ron Goeree and Paul Gully point out. They have estimated the direct and indirect costs to society of two of the most prevalent STDs, chlamydia and gonorrhoea, both of which are significant risk factors for infertility. These costs include hospitalizations, professional billings, drugs, and lost productivity as a result of treatment. Their findings — that the total burden in 1990 ranged



from a low of \$41 million to a high of \$123 million for chlamydia and from \$29.5 million to \$74 million for gonorrhoea — underscore the costs to society of not actively pursuing effective prevention of STDs.

Prevention programs have to achieve two aims — to transmit information and to alter behaviour. The latter aim has been shown to be particularly difficult to achieve with adolescents, the group most at risk of contracting and transmitting STDs. Louise Hanvey and Dianne Kinnon focus on the social factors that are involved in the transmission of STDs and identify how knowledge of these factors can be used to design prevention programs that are effective at bringing about the behavioural changes necessary to prevent the transmission of STDs. These authors direct our attention beyond the health care system to the role of other systems dealing with social factors and values, including the education and social welfare systems.

It must be borne in mind that many aspects of effective prevention lie outside the health care system. With regard to preventive programs supported from health budgets, however, it is evident that resources for health care are not likely to increase, so that any expenditure on prevention within the health care system must come from a shift of priorities within that system. Part of the reluctance to shift resources to prevention within the system arises from the lack of evidence of the effectiveness of prevention programs.

Too often, says Ron Goeree, prevention programs are introduced without evidence of either clinical effectiveness or economic efficiency. He examines the feasibility of applying various models for economic evaluation, such as cost-benefit analysis, cost-effectiveness analysis, and cost-utility analysis, to prevention programs. He finds a lack of standardization and coordination in the administration of STD prevention programs, so that collecting the information necessary to carry out these analyses is not currently possible. Prevention programs cannot be evaluated beyond a qualitative analysis in this situation, and he points out the necessity for greater coordination of efforts to allow assessments.

As Annalee Yassi points out, existing prevention programs designed to reduce exposure to hazards in the workplace are rarely specifically designed to focus on infertility. Reproductive health hazards have unique features that require attention, however, including differences in male and female physiology, the particular susceptibility of the fetus to agents that might not pose a threat to the adult worker, and the specific demands of pregnancy. She points out the danger of using differences in male and female physiology as an excuse for discriminatory policies that are not well supported by scientific literature. She provides recommendations on how prevention program evaluations should be structured, with integration of research, public policy, and workplace health and safety protection considerations and particular emphasis on criteria- and satisfaction-based outcomes.

Finally, Brian Hyndman et al. examine the various models of prevention and their potential application to infertility prevention. The study notes the strengths and weaknesses of a wide range of prevention models and their applicability to the specific situation of infertility prevention. The wide range of choices available in any effort to prevent infertility underscores the need for effective evaluation of programs to provide crucial information about the effectiveness of various approaches. The study also makes the point that prevention of infertility is a wide-ranging undertaking that involves individual behaviour and social context, and that it takes place in many arenas, including the community and the workplace.

## Conclusions

Taken together, the studies in this volume outline the reasons why allocating substantial resources to prevention programs and strategies is a difficult undertaking, the factors involved in ensuring that we have evidence that such allocation is warranted, and data on the costs of not preventing infertility. The obstacles identified by Dr. Thomson are addressed in the papers that follow, which demonstrate that greater emphasis on prevention may not only alleviate personal suffering, but help to ensure the health of our population and a more appropriate allocation of resources.

The effectiveness of the great majority of prevention programs — like the effectiveness of most infertility treatments — remains unproven. Both prevention and treatment programs should be approached in the same way when deciding about resource allocation — both need to be evaluated rigorously before they are disseminated widely, and then regularly after that to determine their continuing effectiveness. Despite the difficulties, there is enough evidence to show that some prevention programs are effective and that they certainly can be evaluated. It is clear that, to tackle the prevention of infertility effectively, a coordinated strategy in many areas of Canadian society is needed.



# **Prevention of Infertility: Overcoming the Obstacles**

Alistair Thomson



## **Executive Summary**

Prevention of infertility is not currently a health policy priority in Canada, nor are there any programs currently in place that have prevention of infertility as their main objective. On examination, this is not surprising, given the obstacles to putting prevention of infertility on the political agenda. There are at least 10 such obstacles:

- “infertility” has not been defined;
- the prevalence of infertility has not been established;
- it is not clear whether the desire to have children is a fundamental human need or simply a matter of personal choice;
- the relative importance of the risk factors that may lead to infertility is unknown;
- the cost-effectiveness of intervention has not been — and perhaps cannot be — demonstrated;
- treatment of infertility is not generally regarded as “medically necessary”;
- responsibility for prevention of infertility is unclear;



## 2 Prevention of Infertility

- there is no organized constituency pressing for prevention programs;
- from the perspective of health policy, prevention of infertility per se ranks very low in comparison with other pressures on the health care system; and
- perhaps in light of the above, there is no political will to make prevention of infertility a priority.

In an endeavour to overcome at least some of these obstacles, the Commission may wish to consider recommending the following to the federal government:

- as a first priority, current efforts to control the spread of sexually transmitted diseases among adolescents be redoubled in the context of healthy sexuality and reproductive health;
- federal health research funding (through the Medical Research Council and the National Health Research and Development Program) be directed toward establishing the relative importance of the risk factors leading to infertility and to demonstrating the cost-effectiveness, if possible, of preventive interventions;
- the federal and provincial governments, in consultation with health care providers, undertake to clarify the concept of medical necessity for the purpose of determining which services should be insured pursuant to the Canada Health Act;
- a consensus conference be held at an early date to ascertain what is now known about infertility and what can be done to prevent it; and
- Statistics Canada, in consultation with Health and Welfare Canada, determine the prevalence of infertility, defined as the Commission stipulates, and trends in the prevalence of infertility be monitored on an ongoing basis.

## Introduction: Research and Policy

In every system of morality, which I have hitherto met with, I have always remark'd, that the author proceeds for some time in the ordinary way of reasoning, and establishes the being of a God, or makes observations concerning human affairs; when of a sudden I am surpriz'd to find, that instead of the usual copulations of propositions, *is*, and *is not*, I meet with no proposition that is not connected with an *ought*, or an *ought not*. This change is imperceptible; but is, however, of the last consequence. For as this *ought*, or an *ought not*, expresses some new relation or affirmation, 'tis necessary that it shou'd be observ'd and

explain'd; and at the same time that a reason should be given, for what seems altogether inconceivable, how this new relation can be a deduction from others, which are entirely different from it.

David Hume, *A Treatise of Human Nature*, Book III

Why should we be concerned about developing strategies to prevent infertility? Is it so people may satisfy a fundamental human desire to have children? To enhance health status and quality of life? Or is it to obviate the need for new and expensive reproductive technologies?

The famous passage from Hume's *Treatise* cited above serves as a reminder, if one is needed, that no amount of empirical research *by itself* will reveal what policies to adopt and what programs to implement. Values must also be taken into account, and differences in values can be difficult, if not impossible, to reconcile. This is nowhere more obvious than in issues relating to human reproduction. There are deep divisions even within the medical profession between those who regard new reproductive technologies as exciting developments at the very frontiers of science, and those who dismiss them as "veterinary medicine."

These differences in values do not mean that empirical research is irrelevant to policy development. While it is never sufficient, such research can be useful in many ways. To the extent that differences in value judgments stem from differences in factual beliefs, and to the extent that empirical research findings can dispel misunderstandings about what is the case, such findings can provide a basis for consensus about what action to take. Policy decisions that are predicated on solid information are more likely to have happier outcomes than those that are based on nothing more than the latest public opinion poll, or those that fly in the face of the evidence. Another aspect is that lack of empirical research often provides a handy excuse for inaction by policy makers. In periods of fiscal restraint, such excuses are more than welcome.

It is not surprising that prevention of infertility is not a health policy priority in Canada, given the obstacles to putting prevention of infertility on the political agenda. There are at least 10 such obstacles:

1. the concept of infertility is unclear;
2. the prevalence of infertility has not been established;
3. it is not clear whether the desire to have children is a fundamental human need or simply a matter of personal choice;
4. the relative importance of the risk factors that may lead to infertility is unknown;
5. the cost-effectiveness of intervention has not been — and perhaps cannot be — demonstrated;
6. treatment of some kinds of infertility is not generally regarded as "medically necessary";

7. responsibility for prevention of infertility is unclear;
8. there is no organized constituency pressing for prevention programs;
9. from the perspective of health policy, prevention of infertility ranks very low in comparison with other pressures on the health care system; and
10. perhaps in light of the above, there is no political will to make prevention of infertility a priority.

The purpose of this report is to suggest ways to overcome at least some of these obstacles. These suggestions are based on my experience as Director of Health Policy, Health and Welfare Canada, on a review of the material gathered by the Commission to date, and on recent interviews with a number of "key informants." This document expresses my own views, and does not necessarily represent those of the Royal Commission on New Reproductive Technologies.

## Why Prevention Is Not a Priority

There are many well-established and successful disease prevention and health promotion programs in Canada. They range from pasteurization of milk and immunization of children to a ban on tobacco advertising and a "safe sex" campaign for AIDS. They include programs as diverse as screening immigrants for tuberculosis, and the enforcement of seat belt legislation.

Prevention of infertility is not among these programs, apparently because infertility is neither life-threatening nor affects large numbers of Canadians. In order to make prevention of infertility a health policy priority, a number of obstacles would have to be overcome.

## Definitions of "Infertility"

There is a great deal of confusion about what infertility is and how the term "infertility" is to be defined.

The Office of Technology Assessment (OTA), in a report titled *Infertility: Medical and Social Choices*, notes "infertility has been characterized as a disease, disorder, disability, handicap, illness, syndrome, condition, or condition caused by disease." It goes on to conclude that "it is useful to talk about infertility as a clinical problem for which the medical community can sometimes offer a remedy" (U.S. Congress 1988, 36-37).

Definitions of "infertility" are couched either in terms of conception or in terms of birth. Sometimes definitions are offered that attempt to encompass both. For example, Barbara Menning defines infertility as "the inability to conceive a pregnancy after a year or more of regular sexual relations without contraception, or the inability to carry pregnancies to a



live birth" (Menning 1988, 4). According to the World Health Organization, a couple would be considered infertile if they were unable to achieve conception within two years of unprotected intercourse. (One key informant suggests that adoption of a "sliding scale" may be appropriate, with a one-year stipulation for couples in their twenties, two years for couples in their thirties, and three years for couples in their forties. One external reviewer of this paper, while accepting the concept of a sliding scale, suggested that the time periods should be reversed on the grounds that there is less time left to undergo fertility evaluation, treatment, and investigation of possibilities of adoption.)

The concept of infertility is both vague and ambiguous. It is vague in the sense that there is no non-arbitrary cut-off in the period required for conception, and it is ambiguous because it appears to apply to conception in some contexts and to birth in others. What is needed for policy purposes is a clear, stipulative definition of "infertility" that will help policy makers understand the nature of the problem, and permit researchers to measure its magnitude.

It is not enough to report on the various ways the concept of infertility can be understood. The Commission should make a recommendation on how the term "infertility" should be used for policy and research purposes. This recommendation should, to the extent possible, reflect "ordinary" usage, while recognizing that such usage is simply not precise enough to be useful for survey purposes.

It is worth noting, in passing, that there are also some difficulties with respect to the concept of prevention itself. Walter O. Spitzer defines "prevention" as

any intervention that reduces the likelihood that a disease or disorder will affect an individual or that interrupts or slows the progress of the disorder. Primary prevention reduces the likelihood that a particular disease or disorder will develop in a person. Secondary prevention interrupts or minimizes the progress of a disease or irreversible damage from a disease by early detection and treatment. Tertiary prevention slows the progress of the disease and reduces the resultant disability through treatment of established disease. (Spitzer 1990, 4)

It is difficult to see how these standard definitions and distinctions apply to infertility. Tertiary prevention doesn't look like prevention at all and secondary prevention of, say, a sexually transmitted disease could well be primary prevention of infertility. Although these distinctions may be useful in some contexts, they are not as much use in developing policies and programs related to infertility.

## The Problem of Prevalence

How many couples in Canada want to have children of their own and find they cannot? The policy implications are very different if the number is small and declining, or if it is large and growing.

It is interesting to note in this context that the total fertility rate has been rising in recent years as more "baby boomers" choose to have children. Statistics Canada reported recently that the total fertility rate in 1990 was 1.86, up sharply from 1.65 in 1986 (Strauss 1992, 1). This is still below the natural replacement rate of 2.1 needed to stabilize the growth of Canada's population; the instrument chosen to meet that objective is, of course, immigration policy.

While the total fertility rate does not indicate the prevalence of infertility, when the fertility rate is rising rapidly, the prevalence of infertility somehow seems less important in a policy context.

In theory, the justification of strategies to prevent infertility should include well-established baseline data as well as a clear indication of any trends. In practice, such information may not be available, and while baseline data may be difficult to obtain, trends may be even harder to estimate. The fact that more couples are choosing to have children may bring more cases of infertility to light, which in turn may increase the demand for new reproductive technologies. Moreover, as new reproductive technologies become available, couples who previously felt that their problem could not be solved may seek treatment. But it would be a mistake to conclude that there is an underlying increase in the prevalence of infertility.

## Basic Need Versus Personal Choice

While the desire to have children of one's own can be very strong, it does not follow that this desire is a fundamental human need. The distinction between basic needs and personal choices is important in a policy context, because if the desire to have children is viewed as a basic need, it is easier to make the argument that the state should undertake special measures to help ensure that individuals can fulfil this need. If having children is simply viewed as the exercise of "consumer" choice, this argument is more difficult to justify.

Some 129 000 Canadians chose to be surgically sterilized in 1990-91: there were 66 693 tubal ligations and 62 101 vasectomies performed in that year. In addition, 80 453 women had therapeutic abortions in 1991. All of these procedures were covered under provincial health insurance plans.<sup>1</sup> These data do not indicate how many of these individuals already have children of their own, but they do reveal that a significant number of Canadians are choosing surgery paid for by the state to prevent or terminate unwanted pregnancies.

It is interesting to note that while all provinces, except Prince Edward Island, are prepared to pay for sterilization and abortion under their health insurance plans, no province, except Ontario, is prepared to pay for assisted human conception, and Ontario is contemplating de-insuring some procedures like *in vitro* fertilization (IVF). This seems to indicate that Canadian policy makers favour the view that having children is a matter of personal choice, at least insofar as public expenditures are concerned.

## Ranking of Risk Factors

The Commission has identified two risk factors as the most important, as far as infertility is concerned: sexually transmitted diseases (STDs) and delayed childbearing. In addition, there are other risk factors that may play a role. These include workplace hazards, endometriosis, substance abuse, excessive exercise, eating disorders, prescription drugs, iatrogenic factors, and environmental exposures.

There is general agreement that STDs and delayed childbearing are the most significant risk factors. Beyond this, information on relative importance of the factors on a population basis is not available.

From a policy perspective it appears that controlling the spread of STDs should be given the highest priority. They are the most significant risk factor, and contracting these diseases can be prevented.

Delayed childbearing may be more difficult to deal with, since workplace, educational, social benefits, and child care policies would all need to be changed to enable women to try to have families during their more fertile years.

The Office of Technology Assessment concludes the following with regard to prevention:

Only an estimated 20 percent of infertility — that caused by sexually transmitted diseases — is clearly amenable to prevention strategies. In those instances, curative medicine equals prevention of sexually transmitted diseases. Otherwise, the majority of cases of infertility are difficult, if not impossible, to prevent.

Prevention of male infertility is an enigma and will likely remain so as long as most male infertility is caused by reduced sperm count of unknown origin and little research addresses this question. Among women, tubal obstruction, endometriosis, and disorders of ovulation are the principal factors leading to infertility. Some tubal obstruction is preventable by avoiding sexually transmitted diseases, but specific prevention strategies for endometriosis and anovulation are largely unknown.

The biology of female fertility makes maternal age, especially beyond age 35, a factor in infertility. Although no social prescription fits all couples seeking to conceive, couples enhance their chances of success by maximizing the number of months or years devoted to attempts at conception, and doing so before maternal age becomes a significant factor.

Education of individuals contemplating sexual activity and of medical care providers about reproductive health and sexually transmitted diseases plays an important role in reducing threats to fertility. Gaps in their knowledge and even broader gaps in scientific understanding of normal and abnormal male and female reproductive physiology impede further progress in preventing infertility. (U.S. Congress 1988, 91-92)

In policy terms, the upshot of this major American study appears to be fourfold: avoid sexually transmitted diseases; if possible, have children



sooner rather than later; provide better training for physicians in the area of reproductive health; and do more basic research.

### Cost-Effectiveness of Intervention

In times of fiscal restraint it is essential, or at least highly desirable, to demonstrate the cost-effectiveness of any new policies and programs. This is difficult in the case of strategies developed to prevent infertility. Cost-effectiveness studies in the health area are designed to facilitate comparisons between alternate interventions. Costs include the costs of the intervention (plus the costs of treating any side-effects), less the savings in treatment because disease is prevented. Effects include increases in life expectancy and improvements in health status.

Designing and carrying out cost-effectiveness studies of infertility prevention strategies would be challenging, to say the least. Infertility, which is less a "disease" than a "condition," does not seem to affect life expectancy or other conventional measures of health status. In fairness, it should be noted that few of the new — or old, for that matter — health technologies have been subjected to cost-effectiveness analysis.

It is a commonplace assumption that prevention is always less costly than treatment. But as Louise B. Russell has convincingly demonstrated in her recent book *Is Prevention Better Than Cure?*, this is not necessarily so. Prevention strategies rarely, if ever, reduce health care costs. What they may do if they are successful is provide better health outcomes at increased cost. But since there is no prospect for new money for infertility prevention strategies, new strategies may have to be "piggybacked" on existing programs that are relevant to reproductive health. This could make existing programs *more* cost-effective and hence help to preserve them. With any luck, this could even be a "win-win" scenario.

### Medical Necessity

As noted above, most provinces do not cover procedures such as IVF under their public health insurance plans, so the costs of assisted human conception are borne largely by the individuals wanting to have children rather than their provincial governments. Hence, the argument runs, the provinces have less interest in preventing infertility than they would if they had to bear the costs of treating it. But should these procedures be provided as insured benefits?

In exchange for making health-related contributions to the provinces under the Established Programs Financing arrangements, the federal government expects the provinces' health insurance plans to comply with certain principles. The principles in question are embodied in the Canada Health Act: universality, accessibility, comprehensiveness, portability, and public administration.

Three of the so-called "program criteria" in the Canada Health Act — universality, portability, and public administration — are clear enough for

the purpose of administering the legislation. This is not to say there are no problems with these three criteria, but they are not *conceptual* problems. The other two criteria — accessibility and comprehensiveness — require clarification.

Issues of accessibility, or “reasonable access” to insured services by insured persons, appear to fall into three categories: the first, financial access, appears to have been largely resolved by the application of the Canada Health Act provisions concerning dollar-for-dollar reductions in amounts otherwise payable to a province in respect of any point-of-service charges for insured services. These provisions, in effect, guarantee first dollar coverage for hospital and medical bills.

The second issue relating to accessibility, geographical access, is more problematic and has to do with the supply and distribution of health care resources across Canada. Clearly, the development of guidelines with which the provinces would be expected to comply would be helpful in this regard.

The third accessibility issue arises in the form of statements like the following: “Women in community X do not have access to *in vitro* fertilization.” In this case it is not clear whether the problem is one of geographical access, i.e., the procedure is simply not available locally; one of portability, i.e., the home province will not pay host province rates when the procedure is performed out-of-province; or, finally, one of comprehensiveness, i.e., the province will not pay for the procedure at all, wherever it is performed.

This brings us to the heart of the matter, the definition of “comprehensiveness” — which health services are, or should be, insured? There appear to be two competing schools of thought. The first is that all health services performed by a recognized health care provider or in a recognized health care facility should be insured, unless they are specifically excluded. This approach, it is argued, helps to ensure maximum benefits for health care consumers by placing the onus on the province to justify any exclusions.

The second school of thought argues there should be a list of insured health services, and any additions to that list would have to be shown to be justified by health care providers. This approach, it is argued, helps to contain costs by ensuring proper assessment of new health care technologies.

In practice, of course, the concept of “medical necessity” appears to inform decisions about what is, or should be, an insured service, and “medical necessity” is itself informed by the opinion of the attending physicians. Recent emphasis on the importance of “evidence-based” medicine should help to clarify the concept of “medical necessity.”

## **Roles and Responsibilities**

Under the Constitution Act of 1867, health, along with education and welfare, falls primarily within provincial jurisdiction. Despite this fact, the federal government has used its unrestricted spending power to influence provincial programming in the health area in the past, initially through the mechanism of 50-50 cost-sharing of health insurance programs.

Though federal influence has been waning in recent years, partly because of the shift to block-funding in 1977 but mainly because of the recent and ongoing reductions in transfers to the provinces under the Established Programs Financing arrangements, the federal government still plays a number of useful roles in the health area. These include support for the provinces' health insurance programs, service delivery to certain special groups, regulation of food and drugs, setting environmental and workplace standards, disease surveillance, screening of immigrants, research support, performing a clearinghouse function for health information, and coordinating interprovincial and international activities. This does not purport to be a comprehensive list of federal activities but it does indicate that the federal government is still an important "player" in health care.

In the development of strategies to prevent infertility, it is not clear which level of government should take the lead. The issue cannot be resolved until it is known what strategies are appropriate. One way out of this "Catch-22" would be for the Commission to develop such strategies and to suggest that the federal government and the provinces get together to define their respective responsibilities.

## **Health Policy Priorities**

The Canadian health system faces a number of serious pressures. Among the pressures generally recognized are population aging, the diffusion of new technologies, the oversupply and maldistribution of physicians, rising public expectations, and the need to develop new disease prevention and health promotion programs in the face of institutional inertia and fiscal restraint.

Because infertility is not a life-threatening condition and is not perceived to affect large numbers of Canadians, it is difficult to see how prevention of infertility could become a health policy priority in its own right. It could, nonetheless, become an important facet of other policies and programs relating to the control of sexually transmitted diseases and, more generally, to reproductive health and healthy sexuality.

## **Constituency**

While many of the individuals or groups who made submissions to the Commission discussed the need for prevention, their recommendations do not appear to stem from any real analysis. Those most concerned about



infertility (i.e., couples who want to have children of their own and who find that they cannot) are less interested in prevention than in treatment.

A former federal health minister once intimated at a small invitational conference sponsored by the Canadian Hospital Association that public hearings are “boring like hell; you don’t learn anything but they’re essential to building a power base.”

This is no doubt sound political advice. But just the opposite seems to have happened in the case of the public hearings sponsored by the Commission: although many individuals and groups emphasized the importance of prevention, the Commission was accused of not listening to what it heard. I do not know whether or not this allegation is justified.

In any case, it would seem to be useful to attempt to reach some sort of understanding among all interested parties with respect to prevention of infertility. One way to do this might be to hold a “consensus conference” on the issue in order to ascertain just what is known and what, if anything, can be done.

## Political Will

Finally, and this seems so obvious as to be hardly worth saying, there must be political will if prevention of infertility is to get on the public policy agenda. Given all of the obstacles to developing strategies to prevent infertility, it is not obvious how ministers could be persuaded to pay much attention to this issue. One way to do so would be to demonstrate that the implementation of such strategies would help relieve some of the pressures on the Canadian health system, if indeed that can be done. Another tactic might be to draw attention to a consensus about what should be done, if such a consensus were to develop.

## Conclusions and Recommendations

It is evident that there are a number of obstacles to putting prevention of infertility on the political agenda, and strategies to prevent infertility are not likely to be robust enough to survive on their own. Instead, they must be “piggybacked” on extant health programs in the areas of reproductive health and healthy sexuality. For example, given that sexually transmitted diseases are a significant risk factor and that adolescents are at the highest risk of contracting STDs, then clearly any healthy sexuality program in which they participate should include information on prevention of infertility. Emphasis, however, would likely be on the importance of self-esteem, avoiding unwanted pregnancies, and avoiding the STDs themselves. Reducing the risk of infertility, while an important consideration, would not be central.



The Commission may wish to consider making the following recommendations to the federal government:

1. as a first priority, current efforts to control the spread of STDs among adolescents be redoubled in the context of healthy sexuality and reproductive health;
2. federal health research funding (through the Medical Research Council and the National Health Research and Development Program) be directed toward establishing the relative importance of the risk factors leading to infertility, and to assessing, if possible, the cost-effectiveness of preventive interventions;
3. the federal and provincial governments, in consultation with health care providers, undertake to clarify the concept of medical necessity for the purpose of determining which services should be insured pursuant to the Canada Health Act;
4. a consensus conference be held at an early date to come to agreement on what is now known about infertility and what can be done to prevent it; and
5. Statistics Canada, in consultation with Health and Welfare Canada, determine the prevalence of infertility, defined as the Commission stipulates, and trends in the prevalence of infertility be monitored on an ongoing basis.

## Notes

1. Health and Welfare Canada, Health Information Division, Policy, Planning and Information Branch. This information comes from the provinces' fee-for-service health insurance data base.

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# **The Effectiveness of Sexually Transmitted Disease Infertility-Related Prevention Programs**

Lynn McIntyre



## **Executive Summary**

There is little evidence in the health science literature to confirm the effectiveness of infertility-related prevention programs. The study focusses on programs aimed at the prevention of sexually transmitted disease (STD)-related infertility. Efforts to identify effective prevention programs are hampered by three factors: limitations of basic science, methodological limitations, and political constraints.

Limitations of basic science include the lack of knowledge about the natural history of infertility, the limited number of efficacious manoeuvres, and the lack of knowledge of preventable causes of infertility.

Methodological limitations include imprecise program evaluation techniques, issues arising in study design, and problems in measuring outcomes in a meaningful way.

Political constraints include the absence of comprehensive programs; the fact that infertility prevention has not been a specific focus of STD control programs; lack of public health innovation in the area; lack of a program delivery infrastructure for feasible expansion of proven programs; lack of political will to establish or evaluate such programs, or even to control STDs; and the redirection of opportunities, funds, and



human resources for the development and evaluation of such programs toward the control of the human immunodeficiency virus (HIV).

The study concludes by proposing a strategy to evaluate the effectiveness of infertility-related STD prevention programs.

## **Introduction**

The reduction of infertility through the implementation of effective prevention programs would be a logical and attractive recommendation for the Royal Commission on New Reproductive Technologies to make. Although several important causes of infertility are related to preventable risk factors, existing programs do not appear to be effective in preventing infertility. This paper outlines reasons for this apparent paradox and proposes an evaluation strategy to redress the gap. The primary focus of the report is the prevention of infertility related to sexually transmitted diseases (STDs).

## **Evaluating Infertility-Related Prevention Programs**

The reasons for a failure of the health science literature to provide evidence of the effectiveness of infertility-related prevention programs (IRPP) can be classified broadly as limitations of basic science, methodological limitations, and political constraints.

### **Basic Science Limitations**

Three basic science deficiencies undermine attempts to identify effective IRPP: the lack of knowledge of the natural history of infertility, the limited number of efficacious manoeuvres, and the lack of knowledge of preventable causes of infertility.

#### ***Natural History***

We do not know the natural history of the infertility-vulnerable cohort. Studies of sexuality and of STDs are largely cross-sectional.<sup>1</sup> Are there differences in STD-related infertility when cohorts are followed? Is there an exhaustion of susceptibles, an age-of-risk plateau? Of 1 000 newly sexually active women, how many become infected with a STD; how many spontaneously clear their infection; how many subsequently develop cervicitis, subclinical pelvic inflammatory disease (PID), fulminant PID, infertility? Any program intended to reduce infertility must achieve results more favourable than the natural history of the condition.

### ***Efficacious Manoeuvres***

Before programs for infertility-related prevention can be evaluated, their components must be known to be efficacious. A manoeuvre efficacious in preventing STD-related infertility could act at several critical points in the path to infertility. It could reduce the incidence of STDs so that women would not be so much at risk; reduce the possibility of a woman risking exposure; reduce the possibility of her acquiring a STD if exposed; or treat an infection before tubal damage occurred.

The known efficacious components of IRPP include vigorous contact tracing with appropriate therapy and epidemiological treatment of contacts;<sup>2</sup> use of mechanical and chemical barriers to STDs;<sup>3</sup> patient education to increase compliance with STD therapy;<sup>4</sup> screening for STDs in certain high-risk groups;<sup>5</sup> and the administration of anti-microbial therapy according to standard protocols.<sup>6</sup> However, more is unknown than is known about the prevention of STD-related infertility.

Questions include the following:

- (a) What level of reduction of STD incidence would permit women to engage in sexual activity risk free?
- (b) What is the best method of contact tracing?
- (c) What strategies influence women to avoid STD exposure?
- (d) What evidence have we that providing women with decision-making and negotiating skills as part of sexual education programs enhances their skills during sexual engagement?
- (e) How do we change sexual behaviours, especially in adolescent women?
- (f) Will a vaccine prevent exposed people from acquiring infection?
- (g) What is the incubation period of salpingitis? How soon after infection does tubal damage begin?
- (h) What would motivate physicians to adopt the well-established therapeutic protocols for STDs? and
- (i) Who should be screened for STD? Where should screening and STD care be offered?

### ***Preventable Causes of Infertility***

Infertility is a complex multi-causal phenomenon.<sup>7</sup> Risk data derived from retrospective studies provide evidence of associations rather than causal factors.<sup>8</sup> A program that reduced risk factors might not be successful in preventing infertility if such factors were confounders of the association. Further study is required to identify true "causes" of infertility.

## Methodological Limitations

### *Epidemiology and Program Evaluation*

Epidemiology is an uncertain science dealing with probabilities and inferences. Similarly, program evaluation techniques, based usually on an epidemiological design, are imprecise and have methodological limitations and difficulties in interpreting observations of free-living populations.

### *Study Design Issues*

Significant study design issues may inhibit evaluations being conducted on STD-related infertility prevention programs. What is the purpose of the program — is it to reduce STD incidence, reduce STD prevalence, reduce PID, or prevent infertility in women? An evaluation could be conducted using one of three designs: randomized controlled field trial, quasi-experimental trial, or a before/after study. Each design has advantages and disadvantages. What would be the unit of evaluation, the individual or the population? The populations under study must be comparable, and the co-intervention and contamination of the study groups must be avoided. Large sample sizes would be required to demonstrate an effect. How large an effect would merit the necessary deployment of resources? Other jurisdictions must be able to implement the program, and its results must be applicable to the others as well. Program evaluation would need to determine that the program was implemented as intended. In addition, an IRPP evaluation would benefit from qualitative research techniques.

### *Measuring Outcomes*

A major problem in conducting an effectiveness evaluation of an IRPP would be to decide on relevant outcomes and on how they would be measured. The outcome of infertility is in the future, hard to define, and multi-causal. Ectopic pregnancies are good measures because almost all are recorded as hospital separations.<sup>9</sup> Women with severe tubal occlusion may not be able to implant ectopically, so a reduction in ectopic pregnancies may not signal program success. Admission to hospital for PID could be used as a measure; however, it is a partial outcome because not all women with PID are admitted to hospital, and not all women with tubal damage have a history of PID.<sup>10</sup> Incidence rates of STDs have serious reporting biases;<sup>11</sup> a study would have to employ uniform and enhanced surveillance methods and apply accurate diagnostic tests. The monitoring of individuals for STD incidence would be labour-intensive and expensive, and require individual consent. Most of these outcomes are short-term, indirect measures of infertility. Even if several years of observation of STD incidence in a large sample of adolescent women exposed to a program showed reduction in STD, it would be somewhat inappropriate to conclude that the program reduced infertility.

Other sexual health indicators that a program might address, such as regular condom use, number of sexual partners, and use of sexual



negotiation techniques, require subjects to recall information and report honestly, and may be more affected by extraneous factors than by the program.

## Political Constraints

Several barriers in the politics of health care limit the availability of IRPP for evaluation. They include (a) the absence of comprehensive programs (most are population-based STD control programs); (b) the fact that infertility prevention has not been a specific focus of STD control programs; (c) lack of public health innovation in the area; (d) lack of a program delivery infrastructure for feasible expansion of proven programs (a program might have to be hospital-based, delivered through public health, or free-standing — coordinating mechanisms are weak); (e) lack of political will to establish or evaluate such programs, or even to control STDs; and (f) the fact that opportunities, funds, and human resources for the development and evaluation of such programs have been redirected toward the control of the human immunodeficiency virus (HIV).

Although many components of a program that might reduce STD-related infertility operate in public health units,<sup>12</sup> schools,<sup>13</sup> physician offices,<sup>14</sup> and youth clinics,<sup>15</sup> no fully operational, coordinated community or province-wide programs exist. Provinces using model standards for STD control, within the domain of public health, have partially established a programmatic approach to STDs.<sup>16</sup> Moreover, provinces have been able to mount other types of comprehensive programs, as exemplified by immunization,<sup>17</sup> tuberculosis control,<sup>18</sup> and heart health programs.<sup>19</sup>

The following is an example of a proposal for the evaluation of an infertility-related prevention program.

## Proposal for an Effectiveness Evaluation of an Infertility-Related Prevention Program

### Objective

The objective of the program would be to reduce the burden of infertility by preventing or modifying specific risk factors for the acquisition of STDs in women from 15 to 24 years of age.

### Study Design

The study would be a community effectiveness study<sup>20</sup> conducted in five sites according to a randomized controlled field trial design. Each site participating would implement core components of a comprehensive STD prevention program and would test one enhanced component of the program to determine which components constitute effectiveness-limiting steps. Baseline information on STD occurrence in these sites would be



available before program implementation so that past and present performance could be compared. Participating programs would also be compared with each other. In addition, appropriate control communities and counties would be identified after existing data were reviewed. Regularly collected provincial data throughout the study period could be another source of comparative data.

## Population

The unit of analysis would be the population, rather than individuals. Three moderately sized urban centres and two rural counties would be chosen to implement the program. These sites should be chosen from one province and should share similar socioeconomic and demographic profiles. Nova Scotia would be an excellent provincial site because it offers only rudimentary elements of STD control (i.e., only one designated STD clinic in the province, no free drugs other than prescribed through the Halifax-based STD clinic, almost total reliance on contact self-referral, no provincial standards for STD control, non-mandatory sexual education in schools, no screening of high-risk groups) and because it is a relatively ethnically, economically, and socially homogeneous population. Suggested urban centres could be Dartmouth, Truro, and Antigonish. Rural counties could be Pictou and Yarmouth. The 1991 Census population of women between 15 and 24 years of age would constitute the target population (approximately 15 000). Comparison communities could be Halifax (suitable for Dartmouth control), Wolfville (also a university town) for Antigonish, Glace Bay for Truro, and Lunenburg and Guysborough counties could be controls for Pictou and Yarmouth, respectively.

## Time Period

The study would require one year's baseline data collection, during which time program planning, pilot testing, and program initiation would occur. This would be followed by two years for program implementation and a final 18 months for continued program operation, data collection, and data analysis. The total duration of this study would be four and a half years.

## Program Description

The formula of Tugwell et al.<sup>21</sup> for community effectiveness would form the theoretical framework of the study and would guide program development and evaluation:

$$\text{Community effectiveness} = \text{efficacy} \times \text{diagnostic accuracy} \times \text{health provider compliance} \times \text{patient compliance} \times \text{coverage}.$$

The core comprehensive STD prevention program would follow the principles of STD control, namely (1) determining the size and nature of the problem; (2) provision of adequate facilities for diagnosis and treatment; (3)

case finding, including contact tracing, epidemiological treatment when appropriate, and screening of high-risk groups; and (4) health education to providers on appropriate management and to young women and their partners to promote the adoption of risk-reducing behaviours.<sup>22</sup> These components would be developed using known efficacious manoeuvres.<sup>23</sup> These programs should be multi-focussed, collaborative, and community-oriented.

By random assignment, one urban community would use vigorous contact-tracing strategies as its enhanced component because this has been touted as one of the most efficacious manoeuvres for STD control.<sup>24</sup> Another urban centre would enhance provider compliance through education, quality assurance monitoring, and incentives. The third urban centre would enhance the ability of primary care physicians and other providers to detect STDs through improved laboratory and rapid diagnostic services; also, this centre would offer high-risk women screening opportunities. One randomly chosen rural county would enhance coverage of appropriate services through the establishment of a dedicated reproductive health centre and a youth clinic. The second rural county would develop patient education and outreach programs to enhance patient compliance to seek treatment, refrain from sexual activity during treatment, comply with therapy, refer partners for care, and return for a test of cure.

## Process Evaluation

Program implementation would be monitored throughout to determine that all components were delivered and to give feedback to program delivery personnel. For example, health provider compliance could be monitored by determining whether or not appropriate diagnostic and management actions were performed. Patient compliance is also measurable as completed courses of therapy, attendance at test-of-cure visits, number of contacts referred per patient, and abstinence from sexual activity during therapy. This information could be ascertained indirectly through interviews or directly if such monitoring as pill counts were undertaken. Coverage may be determined through counts (number of visits to clinic, number of women screened) or estimates (students exposed to information in health class, percentage of women indicating awareness of the program).

## Outcomes

The outcome of an epidemiological study of community effectiveness ideally would be expressed in terms of the percentage reduction in the total overall burden of STD in the sexually active, nulliparous, female population. Data to discern the outcome would be derived from a well-developed surveillance system for STDs. Other data would be collected from administrative data bases.

The main outcome would be the reduction in incidence rates of STDs among young women between 15 and 24 years of age. Another indirect

measure of STD control might be to track the percentage of positive tests (i.e., percentage of positive chlamydia isolations to all tests for chlamydia). A higher number of contacts followed per case is a marker of good contact tracing. Organism sensitivity profiles could be used to track the control of resistant organisms.

Numerous secondary outcomes would contribute to the evaluation of program effectiveness. Ectopic pregnancy rates in the target population could be tracked over time, although the period is short, and the ratio of ectopic pregnancies to intrauterine deliveries could be calculated. PID admissions would be another marker.

In addition, a reduction of HIV and cervical neoplasia might be tracked through communicable disease reports and the cancer registry, respectively. Indirect measures of safer sexual behaviour could include condom sales and, through questionnaires administered to a sample of young women, reported condom use, history of STD, or outpatient-managed PID.

## Qualitative Data

A trained qualitative researcher would gather information on program effectiveness through such activities as focus groups with young women about their sexual attitudes and behaviours, observations of shifts in community norms, and impact on providers and parents. It would be interesting to track a cohort of 20 women per site over the study period to observe program impacts on them.

## Budget Estimate

Approximately \$1 000 000 would be required for direct program development and evaluation costs. This sum excludes costs for program delivery staff (other than site coordinators) and health care practitioners, regular STD testing and treatment, and capital costs for upgrading health facilities. Program evaluation personnel (accounting for 70 to 80 percent of project costs) would include one project director, one biostatistician, five site coordinators, three clerical/data support personnel, and one qualitative researcher.

## Notes

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# The Burden of Chlamydial and Gonococcal Infection in Canada

Ron Goeree and  
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## Executive Summary

Among the more than 30 sexually transmitted disease pathogens, *Chlamydia trachomatis* and *Neisseria gonorrhoeae* are two of the most prevalent in Canada. While the incidence of gonorrhoea appears to be decreasing, the change in that of chlamydia cannot yet be determined because it only became nationally reportable in Canada in 1990. (There were 50 384 cases reported in 1989-1990.) Early detection of these diseases is important because they are often asymptomatic, especially among women (up to 80 percent of chlamydia cases, according to some estimates). If untreated, chlamydia can result in serious conditions that affect the reproductive health of women, such as pelvic inflammatory disease (PID), tubal infertility, and ectopic pregnancy.

This study attempts to estimate the direct and indirect cost to society — the burden of illness — of chlamydia and gonorrhoea. Although there are other infections and complications, the study focusses on the most important infections and complications that can result from the two pathogens, namely, male urethritis and epididymitis, uncomplicated female cervicitis and urethritis, PID, infertility, ectopic pregnancy, and chronic pelvic pain. The costs of hospitalization,

professional billings, drugs, and productivity lost as a result of treatment (an indirect cost whose inclusion is controversial) are calculated.

Because the authors frequently draw on estimates over which there is no consensus in the literature, they calculate the burden of illness based on a range of low, base, and high estimates. These are broken down by gender and by age, focussing on the age group that is most at risk of contracting chlamydia and gonorrhoea, the 15-24 age group.

The authors conclude that the total burden of illness of the two diseases in 1990 was sizable; their estimates range from \$41 million to \$123 million for chlamydia and from \$29.5 million to \$74 million for gonorrhoea (males and females combined). The large majority of the cost for females was for treating PID. The 15-24-year-olds accounted for a large part of the total burden of illness for chlamydia and gonorrhoea. A large proportion of the cost of both diseases was accounted for by the loss of productivity; the authors call for more research into whether it should be included in burden-of-illness studies. They point out that more sexually transmitted diseases research, particularly into chlamydia and gonorrhoea, and more aggressive prevention programs, could result in considerable savings.

## Introduction

Sexually transmitted diseases (STDs) are the most commonly reported communicable diseases in Canada. There is a large number of organisms, both bacterial and viral, that are transmitted primarily through sexual contact. Undetected and untreated STDs can lead to a number of chronic diseases such as pelvic inflammatory disease (PID), ectopic pregnancy and infertility, and chronic and acute diseases in infants due to maternal infection. Consequently, STDs are a direct source of pain and discomfort and can have far-reaching emotional, biological, and economic consequences in those affected, their families and friends, and society in general.

This report focusses on two STDs that have been demonstrated to have a direct and substantial impact on the reproductive health of Canadian adults, namely, chlamydial infection and gonorrhoea. Using a societal-prevalence-based approach, the total direct and indirect costs of both STD pathogens and their associated sequelae are estimated for Canada for the 1990 calendar year.

## Chlamydial Infection and Associated Sequelae

*Chlamydia trachomatis* is recognized today as the most prevalent STD pathogen in Canada. It is also considered one of the most important STD pathogens because of the severity of its long-term consequences. The most significant long-term consequences for the reproductive health of women

include pelvic inflammatory disease (PID), ectopic pregnancy, and tubal infertility. Schachter (1990) estimates that 300 million cases of chlamydial infection are reported annually worldwide. It became nationally reportable in Canada in 1990 and 50 384 cases, or 216.8 per 100 000 population, were reported in 1989-1990 (Canada, Health and Welfare Canada 1991). Most reported cases (99.5 percent) involve the genital tract, 0.4 percent involve the eye, and 0.1 percent involve the nasopharynx (Canada, Health and Welfare Canada 1988a). The highest-risk age groups for chlamydia are 15-19 and 20-24 years (their rates were 890.1 and 1 014.7 per 100 000, respectively) and overall, there is a higher rate of reported cases among females than among males (315.6 compared with 102.3 per 100 000). Risk factors for chlamydial infection are multiple sexual partners, new sexual partners, young age, female gender, a history of other STD, and the use of non-barrier contraceptives.

There are 15 serotypes associated with *C. trachomatis*; those associated with genital infection, D-K, are presented in Table 1. Non-gonococcal urethritis (NGU) is a collective term used to categorize urethritis in men in which *N. gonorrhoeae* cannot be recovered. The primary cause of NGU, however, is *C. trachomatis*.

Chlamydial cervicitis may lead to upper genital tract infection (see Table 1) if not treated promptly. A large proportion of *C. trachomatis* infections (up to 80 percent) are asymptomatic, decreasing the likelihood of recognition with regular screening for those at risk. PID is also often asymptomatic, decreasing the opportunity for recognition and appropriate therapy. In addition to ectopic pregnancies and infertility, *C. trachomatis* affects the reproductive health of women in at least three other major ways: through the fear of contracting it, through the fear of recurrence, and through the physical pain and discomfort associated with acute episodes of chlamydia and its long-term sequelae (e.g., chronic pelvic pain).

## Gonococcal Infection and Associated Sequelae

In the past decade, gonorrhoea has been overtaken by chlamydial infection as the most commonly reported STD in Canada. In 1990 in Canada 13 822 cases of gonorrhoea (52.0 per 100 000 population) were reported. This is a decrease of 66 percent (26 919 cases) since 1985 and a decrease of 28 percent (5 288 cases) from only one year ago.<sup>1</sup> This decline can most likely be attributed to improvements in its management, contact tracing programs, more reliable diagnosis of *C. trachomatis* (which may have been misclassified as gonorrhoea), and primary prevention programs following the widespread occurrence of AIDS. The highest-risk age group for *N. gonorrhoeae* is 15-24 years (196.8 cases per 100 000), and overall, there is a higher rate of reported cases for males than females (58.6 compared with 44.7 per 100 000).



**Table 1. Infections and Complications Associated with *C. trachomatis* Infections in Adults**

Serotypes D-K	Men	Women
Infections	Urethritis Proctitis Conjunctivitis	Cervicitis Urethritis Proctitis Conjunctivitis
Complications	Epididymitis Prostatitis* Reiter's syndrome Perihepatitis Sterility*	Salpingitis Endometritis Perihepatitis Ectopic pregnancy Infertility Chronic pelvic pain Prematurity* Stillbirth*

\* Denotes weak strength of association.

Although chlamydia and gonorrhoea have very different incidences, there are many similarities between their infections, complications, and risk factors. Since the majority of female gonorrhoea cases are asymptomatic, the risk of lower genital tract infection spreading to the upper genital tract is also of concern in gonorrhoea cases. The clinical parallels between genital infections caused by *N. gonorrhoeae* and *C. trachomatis* are presented in Table 2.

The vast majority of the infections and associated sequelae of *C. trachomatis* or *N. gonorrhoeae* are associated with the following sites: urethra, epididymis, cervix, and the fallopian tubes. These sites also have the greatest implications for sterility and infertility in the adult population; therefore, the burden-of-illness estimates in this report will focus on them.

Sterility in men as a result of STD pathogens is rare in Canada, since epididymitis is typically unilateral. Bilateral epididymitis occurs in less than 2 percent of men with acute epididymitis. The potential impact of STD pathogens on the reproductive health of women, however, is much more pronounced. Figure 1 is a simplified schematic representation of the relationship between infection with *C. trachomatis* or *N. gonorrhoeae* and the reproductive health of women. Although the percentages down each branch of the tree in Figure 1 for *C. trachomatis* and *N. gonorrhoeae* are different, their sequelae are similar. Apart from the resources devoted to diagnosing or screening for infection, the majority of the costs arising from

**Table 2. Clinical Parallels Between Genital Infections Caused by *N. gonorrhoeae* and *C. trachomatis***

Site of infection	Clinical syndrome	
	<i>N. gonorrhoeae</i>	<i>C. trachomatis</i>
<b>Men</b>		
Urethra	Urethritis	NGU
Epididymis	Epididymitis	Epididymitis
Rectum	Proctitis	Proctitis
Conjunctiva	Conjunctivitis	Conjunctivitis
Systemic	Disseminated gonococcal infection	Reiter's syndrome
<b>Women</b>		
Urethra	Acute urethral syndrome	Acute urethral syndrome
Bartholin's gland	Bartholinitis	Bartholinitis
Cervix	Cervicitis	Cervicitis, cervical metaplasia
Fallopian tubes	Salpingitis	Salpingitis
Conjunctiva	Conjunctivitis	Conjunctivitis
Liver capsule	Perihepatitis	Perihepatitis
Systemic	Disseminated gonococcal infection	Reactive arthritis

**Source:** W. Stamm and K. Holmes, "*Chlamydia trachomatis* Infections of the Adult," in *Sexually Transmitted Diseases*, 2d ed., ed. K. Holmes et al. (New York: McGraw-Hill, 1990).

the two pathogens are for treating PID, ectopic pregnancies, and infertility. Therefore, Figure 1 will form the structure for the cost analysis.

## Methods

### General Costing Approach

Burden-of-illness estimates for *C. trachomatis* and *N. gonorrhoeae* were calculated using a prevalence-based approach. In prevalence-based burden-of-illness studies, point-in-time or period prevalence rates are calculated for each illness, disease, or disability, and the direct and indirect costs associated with it are estimated over a specified time period (usually one year). This type of study is distinct from an incidence-based or cohort cost analysis which estimates the costs of a disease or disability (including sequelae) for a group of patients over an identified period of time, for

example, the lifetime of the cohort. Therefore, although the sequelae of new cases may not occur until some time in the future, the burden-of-illness estimates for the present study are cross-sectional for all members of society for one year only. Some of these costs are associated with new cases and some are associated with the sequelae of cases from previous years.

Costs were calculated based on hospitalization rates, drug regimens, ambulatory treatment protocols, and productivity losses (time off work) as a result of treatment, disease, or disability. Regardless of whether income is lost or not or whether the time is claimed as vacation or sick leave, including productivity losses in cost-of-illness evaluations is controversial. Many researchers argue that time taken off work rarely results in true productivity losses to society because typically the work is either made up later in overtime or more productive work by the employee, or distributed among other workers. The implications of including and excluding productivity losses are included in this analysis.

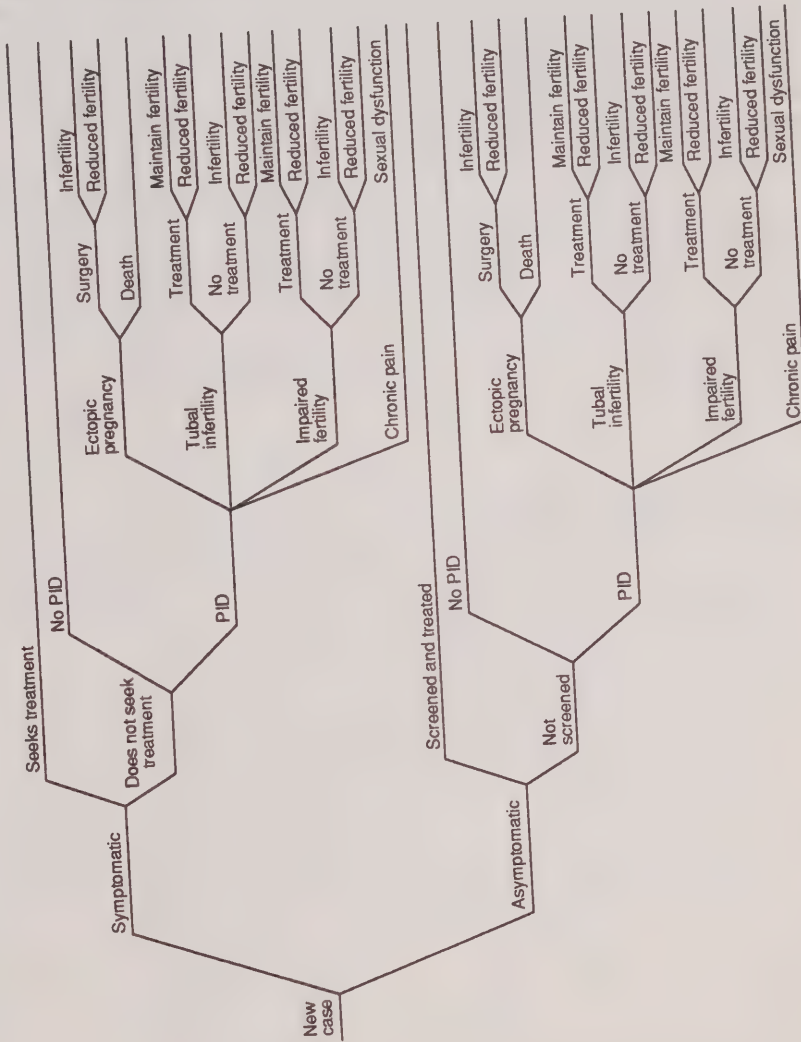
Since this is not a prospective study, there is much uncertainty associated with most of the information used in this analysis. In cost-of-illness studies and economic evaluations it is common practice to vary crucial assumptions in the analysis to test the robustness of the results. Which variables one chooses to vary in a sensitivity analysis depends on how important the assumption or estimate is to the overall results and how much agreement there is in the literature regarding each assumption or estimate. In this study, sensitivity analysis was used where there was a lack of consensus in the literature regarding a crucial assumption and where the assumption or estimate might have a large impact on the overall results. In these cases we included base, low, and high estimates. Although providing a range for each estimate is less specific than a single cost estimate, it does have a major advantage. With a point estimate, one can be almost 100 percent certain that the estimate is incorrect. With a range estimate, however, one can be considerably more confident that the true cost lies within the calculated range. This confidence increases the better the range estimates are around each important assumption. Therefore, the literature surrounding, and the justification for using, each assumption and estimate are discussed in detail.

The cost analysis was conducted from the perspective of society; this is the widest viewpoint, and it incorporates all groups and individuals in society. All costs are expressed in 1990 Canadian dollars.

## Estimating Prevalence

The rates of cure for treatment of either chlamydial or gonococcal infections are greater than 95 percent among compliant patients.

**Figure 1. Sequelae of New Cases of Chlamydial and Gonococcal Infection and Their Potential Effect on the Reproductive Health of Women**





Therefore, if only diagnosed and treated patients were considered, the prevalence of chlamydia or gonorrhoea would be approximately equal to the incidence of new cases. The main problem with this method of estimating prevalence, however, is that a large proportion of patients are asymptomatic. Table 3 presents the range of estimates of the proportion of asymptomatic chlamydia and gonorrhoea cases as reported in the literature. In addition, although the disease is notifiable in most provinces and territories, cases might not be reported. After accounting for asymptomatic and unreported cases, the actual prevalence of each infection may be as high as two to four times the annual incidence rates.

For the purposes of the present study, the prevalence of each infection was assumed to be equal to the incidence for the baseline estimate. Because of the high degree of uncertainty in the actual number of asymptomatic and unreported cases, a conservative prevalence of double the annual incidence was assumed for the high estimate. Since it is generally perceived that the annual incidence is the minimum number of reported cases, these figures were also assumed for the low estimate. Presented in Table 4 is the total number of cases assumed for this study, by gender and by high-risk age group.

**Table 3. Estimates of the Proportion of Chlamydia and Gonorrhoea Cases That Are Asymptomatic**

	Author	%
Chlamydia	Canadian PID Society (1990)	70
	Estany et al. (1989)	77
	Hughes et al. (1989)	78
	Ronald and Peeling (1993)	50-75
	Todd et al. (1988)	80 (female)
	Washington et al. (1985b)	70
	Washington et al. (1987b)	70 (female) 30 (male)
Gonorrhoea	Brunham and Plummer (1990)	70 (male)
	Horsburgh et al. (1987)	30 (male)
	Mårdh (1980)	50 (male) 40 (female)
	Rivlin (1991)	12-50 (male) 50-80 (female)
	Todd et al. (1988)	15 (male) 80 (female)

**Table 4. Total Number of Cases of Chlamydia and Gonorrhoea and Cases in the Highest-Risk Age Group, by Gender, Canada, 1990**

	Low	Base	High
Total chlamydia	50 384	50 384	100 768
Male	11 709	11 709	23 418
15-24-year-old males	6 740	6 740	13 480
Female	37 209	37 209	74 418
15-24-year-old females	26 141	26 141	52 282
Total gonorrhoea	13 822	13 822	27 644
Male	7 681	7 681	15 362
15-24-year-old males	3 513	3 513	7 026
Female	6 024	6 024	12 048
15-24-year-old females	4 079	4 079	8 158

## Diagnostic and Screening Costs

### Laboratory Costs

Laboratory methods of diagnosing *C. trachomatis* and *N. gonorrhoeae* consist of culture and non-culture methods. For both pathogens, cell culture methods are considered the preferred diagnostic test because they have been shown to have 75-85 percent sensitivity and 100 percent specificity. Non-culture methods, however, like the direct fluorescent antibody (DFA) and the enzyme-linked immunoassay (EIA) tests are less time-consuming and costly, and have less specific transport requirements.

Since the total number of diagnostic tests for *C. trachomatis* or *N. gonorrhoeae* that are conducted nationally is not available, the total number conducted in Ontario was extrapolated to the rest of Canada using provincial and national population figures (Canada, Statistics Canada 1987). The province of Ontario was used because it is the largest province and has incidence rates close to national averages. In 1990, the average costs of conducting the principal tests performed in private laboratories, hospitals, and public health laboratories in Ontario for diagnosing *C. trachomatis* were \$26.95 for the chlamydia isolation (L622) and \$5.88 for the non-cultural direct chlamydia assay (L669). For diagnosing *N. gonorrhoeae* using the principal tests, the average cost was \$12.95 for the cervical, vaginal, including GC culture (L625), and \$9.80 for the GC culture (L627) (Ontario, Ministry of Health 1990b). The total number of each test performed in Ontario in 1990<sup>2</sup> and the results of extrapolating these numbers to the rest of Canada are provided in Table 5.

**Table 5. Total Number of Selected Diagnostic and Screening Tests Performed for *C. trachomatis* and *N. gonorrhoeae*, Ontario and Canada, 1990**

	Ontario	Canada
<i>C. trachomatis</i>		
Chlamydia isolation	221 706	613 424
Non-cultural direct chlamydia assay	163 637	452 756
<i>N. gonorrhoeae</i>		
Cervical, vaginal, including GC culture	382 457	1 058 195
GC culture	104 771	289 884

**Source:** Unpublished data from the Laboratory Licensing and Inspection Service, Laboratory Services Branch, Ontario Ministry of Health (Toronto, 1991).

### Professional Billings

Calculating professional billings for the diagnosis of and screening for *C. trachomatis* or *N. gonorrhoeae* is problematic. A number of diagnostic and screening tests accompany annual physical examinations or Pap smears that would be conducted even in the absence of STDs. Since a number of other tests and examinations are performed during annual visits to a physician, it can be argued that physicians' costs associated with annual visits should not be attributed to STD testing. Complicating the issue is the fact that it is common practice and highly recommended to test for *C. trachomatis* and *N. gonorrhoeae* at the same time when either is suspected or among high-risk groups. Therefore, we only included the physicians' costs for follow-up visits that were specifically for *C. trachomatis* or *N. gonorrhoeae*. Since the success rate of treating these two pathogens is so high, only one-quarter of positive cases of chlamydia or gonorrhoea, approximately, return for a follow-up visit.<sup>3</sup> We also assumed that the patient would visit a general practitioner in his/her office or STD clinic, and that a specialist would not be consulted unless complications arose.

General practitioners' fees were calculated using a comparison of provincial fee schedules for major assessments (initial visits) and other assessments (follow-up visits) (Canada, Health and Welfare Canada 1990). Since physician fees vary substantially across provinces, we weighted the averages for physician utilization in each province. The following fees were used in the cost analysis:

- major assessment — \$26.23 (low), \$36.25 (base), \$49.23 (high)
- other assessment — \$13.41 (low), \$17.07 (base), \$21.50 (high)

### ***Productivity Losses***

Including productivity loss (indirect costs) in cost-of-illness studies and economic evaluations is common but controversial. Therefore, in this study the base and high burden-of-illness estimates include productivity losses and the low estimate assumes no productivity losses.

Productivity loss was estimated in three stages. First, in order to conduct sub-analyses, average daily incomes were determined for all employed Canadians, for all employed females, for all employed males, for employed females aged 15-24, and for employed males aged 15-24. These were weighted by labour force participation rates for all Canadians, for all females, for all males, for females aged 15-24, and for males aged 15-24 (Canada, Statistics Canada 1990, 1991a, 1991b, 1991c, 1991d, 1991e). The results are presented in Table 6. These incomes represent the average productivity loss to society of each day of lost employment. The value of homemaking, studying, and leisure activities among the unemployed was not included.

Finally, these average daily incomes were multiplied by an estimate of the time taken off work for diagnostic and screening tests. Since these tests usually accompany an annual physical examination or Pap smear, time taken off work cannot be attributed solely to STD testing, and therefore no productivity loss was included for the initial visit to a physician. For follow-up visits associated with positive cases of chlamydia or gonorrhoea (approximately 25 percent), a half day of lost productivity was assumed.

### **Direct and Indirect Costs of Male Urethritis and Epididymitis**

Treatment costs related to male cases of urethritis also include treatment for complications arising from it. Between 3 percent and 5 percent of male urethritis cases develop the more severe complication, epididymitis (Mroczkowski 1990; Thompson and Washington 1983). Patients with bilateral epididymitis and bilateral occlusion have virtually no chance of being fertile; however, this occurs in less than 2 percent of acute epididymitis cases in Canada (Ronald and Peeling 1993).

### ***Hospitalization Costs***

Urethritis and epididymitis are usually treated on an outpatient basis in Canada. For hospitalized cases, costs were calculated by multiplying average hospital costs by the number of hospital separations and the average length of stay for urethritis and epididymitis separations. Estimating these costs is difficult, because they vary according to the type of hospitalization and the type of hospital. Per diem hospital costs per patient vary substantially between wards within hospitals and across hospitals. They also vary according to whether the hospital is located in a rural or urban location and whether it is a primary, secondary, or tertiary teaching hospital. In addition, they vary across geographic areas within provinces and across provinces. A range of hospital costs was derived from



average per diem hospital costs across provinces and weighted by the number of patient days in each province (Canada, Statistics Canada 1991f). The range of average, per diem hospital costs was estimated to be as follows:

- low (all types of hospitals) — \$409.83
- base (non-teaching, non-long-term-care hospitals) — \$433.71
- high (teaching and non-teaching general hospitals) — \$462.49

**Table 6. Average Daily Income of Canadians, Weighted for Labour Force Participation Rates, by Gender and Selected Ages, Canada, 1990**

	Average daily income (1990 Canadian dollars)
All Canadians	64.42
All females	43.47
Females aged 15-24	34.09
All males	87.32
Males aged 15-24	54.27

According to data from the Laboratory Centre for Disease Control (LCDC) utilizing Health Medical Records Institute (HMRI) records, there were six hospital separations in 1989-1990 for the primary diagnosis of non-gonococcal urethritis.<sup>4</sup> Extrapolating these separations to the province of Quebec (Canada, Statistics Canada 1987), there were eight hospital separations in the whole of Canada. The average length of stay was 5.0 days. Estimates of the proportion of total non-gonococcal urethritis cases due to *C. trachomatis* vary from 25 percent to 72 percent (Mroczkowski 1990; Thompson and Washington 1983; Stamm and Holmes 1990; Bowie 1990; Berger 1990; Parish and Gschnait 1989; Bowie et al. 1981; Randolph and Washington 1990; Sanders et al. 1986). We assumed that 50 percent of the estimated eight hospital separations for non-gonococcal urethritis would be related to *C. trachomatis*. There were 31 hospital separations in 1989-1990 for the primary diagnosis of gonococcal urethritis. Extrapolating these separations to the province of Quebec, there were 42 hospital separations in the whole of Canada (Canada, Statistics Canada 1987).<sup>5</sup> The average length of stay was 4.9 days.

For male urethritis and epididymitis cases in the 15-24 (high-risk) age group, the proportions of total cases of each pathogen for this age group, 58 percent for chlamydia and 46 percent for gonorrhoea, were used (see Table 4).

### Outpatient Cases

Presented in Table 7 are estimates of the number of urethritis and epididymitis cases related to *C. trachomatis* or *N. gonorrhoeae* that were treated on an outpatient basis in Canada in 1989-1990. These estimates were obtained by subtracting the number of hospital separations for these conditions from the total number of male cases of chlamydia and gonorrhoea (Table 4).

### Professional Billings

It was assumed that the general practitioner would be the primary care physician for treating male urethritis and epididymitis. For hospitalized cases, it was assumed that there would be an assessment on admission to the hospital, a daily hospital care visit, and one follow-up visit after discharge from the hospital. The following weighted general practitioner fees were used for the analysis:

- hospital daily visit — \$8.32 (low), \$11.70 (base), \$16.50 (high)
- other assessment — \$13.41 (low), \$17.07 (base), \$21.50 (high)

For outpatient urethritis and epididymitis cases it was assumed that there was one follow-up visit to the physician.

**Table 7. Number of Outpatient Urethritis and Epididymitis Cases Caused by *C. trachomatis* and *N. gonorrhoeae* Among All Males and Males in the Highest-Risk Age Group, Canada, 1990**

	Low	Base	High
<i>C. trachomatis</i>			
Urethritis — all males	11 120	11 120	22 243
15-24-year-old males	6 401	6 401	12 804
Epididymitis — all males	585	585	1 171
15-24-year-old males	337	337	674
<i>N. gonorrhoeae</i>			
Urethritis — all males	7 257	7 257	14 554
15-24-year-old males	3 319	3 319	6 656
Epididymitis — all males	382	382	766
15-24-year-old males	175	175	350

### **Drug Costs**

Although treatment protocols for STDs and associated sequelae usually vary by physician, there are treatment protocols for STDs that are considered standard. Based on Health and Welfare Canada guidelines (Canada, Health and Welfare Canada 1988b),<sup>6</sup> the following treatment protocols were assumed:

- Gonococcal urethritis — Ceftriaxone 250mg IM, and Doxycycline 100mg BID to complete 7 days of treatment
- Non-gonococcal urethritis — Doxycycline 100mg BID to complete 7 days of treatment
- Gonococcal epididymitis — Ceftriaxone 250mg IM, and Doxycycline 100mg BID to complete 10 days of treatment
- Non-gonococcal epididymitis — Doxycycline 100mg BID to complete 10 days of treatment

Since per diem hospital costs include an average cost for medications during the hospital stay, for hospitalized cases of urethritis and epididymitis, medication expenses were only included for treatment outside hospital. Average drug costs were obtained from the Ontario drug benefit formulary (Ontario, Ministry of Health 1990a). A standard pharmacist's dispensing fee of \$8.50 was added to all outpatient prescriptions.

### **Productivity Losses**

For hospitalized cases, it was assumed that, in addition to hospitalized days, three days for urethritis and six days for epididymitis would be lost from normal employment. For outpatient cases, one and five days of normal employment, respectively, were assumed lost (Washington et al. 1987b). More days were assumed lost for epididymitis because it is more serious.

### **Male Infertility as a Result of *C. trachomatis* and *N. gonorrhoeae* Infections**

Infections due to *C. trachomatis* and *N. gonorrhoeae* have been associated with low sperm count, but clinical information on the relationship between infection and male infertility is sparse. Since it is rare for epididymitis to occur bilaterally, it is estimated that fewer than 100 cases of sterility as a result of epididymis infections occur annually in Canada (Ronald and Peeling 1993). Because of the lack of clinical data and in light of the small number of cases, costs associated with male fertility treatment are not included.

### **Direct and Indirect Costs of Uncomplicated Female Cervicitis and Urethritis**

Treatments for uncomplicated female cervicitis and urethritis are similar, so their costs were examined together.

### Hospitalization Costs

As with male urethritis and epididymitis, most uncomplicated female cervicitis and urethritis is treated on an outpatient basis. Data from HMRI indicate there were 2 174 separations for the primary diagnosis of non-gonococcal cervicitis in 1989-1990. Extrapolating these separations to the province of Quebec, there were 2 946 separations in the whole of Canada. The average length of stay was 7.6 days. It was assumed that 50 percent of these separations (1 473) were caused by *C. trachomatis* (Mroczkowski 1990; Thompson and Washington 1983; Stamm and Holmes 1990; Bowie 1990; Berger 1990; Parish and Gschnait 1989; Bowie et al. 1981; Randolph and Washington 1990; Sanders et al. 1986). There were 98 separations for the primary diagnosis of gonococcal cervicitis infections. Extrapolating these separations to the province of Quebec, there were 133 separations in Canada (Statistics Canada 1987).<sup>7</sup> The average length of stay was 4.9 days. For estimates of female cervicitis and urethritis cases in the 15-24 (high-risk) age group, the proportions of total cases for each pathogen for this age group were used, i.e., 70 percent for *C. trachomatis* and 68 percent for *N. gonorrhoeae* (see Table 4).

### Outpatient Cases

Estimates of the number of cervicitis and urethritis cases caused by *C. trachomatis* or *N. gonorrhoeae* that were treated on an outpatient basis in Canada in 1989-1990 are presented in Table 8. They were obtained by subtracting the number of hospital separations for these conditions from the total number of female cases of chlamydia and gonorrhoea (see Table 4).

**Table 8. Number of Outpatient Cervicitis and Urethritis Cases Caused by *C. trachomatis* and *N. gonorrhoeae* Among All Females and Females in the Highest-Risk Age Group, Canada, 1990**

	Low	Base	High
<i>C. trachomatis</i>			
All females	35 736	35 736	72 945
15-24-year-old females	25 106	25 106	51 247
<i>N. gonorrhoeae</i>			
All females	5 891	5 891	11 915
15-24-year-old females	3 989	3 989	8 068

### Professional Billings

It was assumed that the general practitioner would be the primary care physician for treating cervicitis and urethritis. For hospitalized



cases, it was assumed that there would be an assessment upon admission to the hospital, a daily hospital care visit, and one follow-up visit after discharge from the hospital. For outpatient cervicitis and urethritis cases, it was assumed that there would be one follow-up visit to the physician.

### **Drug Costs**

Based on Health and Welfare Canada guidelines (Canada, Health and Welfare Canada 1988b),<sup>8</sup> the following treatment protocols were assumed:

- Gonococcal cervicitis and urethritis — Ceftriaxone 250mg IM, and Doxycycline 100mg BID to complete 7 days of treatment
- Non-gonococcal cervicitis and urethritis — Doxycycline 100mg BID to complete 7 days of treatment

Medication expenses for hospitalized cases of cervicitis and urethritis were only included for treatment outside hospital. Average drug costs were obtained from the Ontario drug benefit formulary (Ontario, Ministry of Health 1990a). A standard pharmacist's dispensing fee of \$8.50 was added to all outpatient prescriptions.

### **Productivity Losses**

For hospitalized and outpatient cases of cervicitis and urethritis it was assumed that, in addition to hospitalized days, one day would be lost from normal employment (Washington et al. 1987b).

### **Sequelae**

The most significant sequelae of cervicitis and urethritis for the reproductive health of women in Canada is PID. It has been estimated that at least 10 percent of non-gonococcal cervicitis and urethritis cases and 10-66 percent of gonococcal cervicitis and urethritis cases go on to develop PID (Washington et al. 1987b; Mårdh 1980; Rivlin 1991; Cates et al. 1990; McGregor et al. 1988; Wasserheit 1987; Bump and Fass 1985). Since this was not a prospective patient follow-up study, the actual number of PID cases in Canada in 1989-1990 was used for the present study.

## **Direct and Indirect Costs of Pelvic Inflammatory Disease (PID)**

PID is defined as an acute clinical syndrome resulting from the spread of micro-organisms from the vagina or cervix to the endometrium and fallopian tubes (Weström and Mårdh 1990). Salpingitis, endometritis-salpingitis, and salpingo-oophoritis are synonyms for PID. It is not easy to diagnose; the most reliable method is laparoscopy. It is estimated that once it is diagnosed, approximately 15 percent of antibiotic treatments are unsuccessful. Fewer than 16 percent of women with PID fit the classical image of PID and fewer than 5 percent appear severely ill. As a result of these "silent" PID cases, 30-81 percent of all PID cases may go undiagnosed (Canadian PID Society 1990; Moore and Cates 1990). There may be as many as 100 000 inpatient and outpatient cases of PID annually in

Canada, most of which are associated with previous STD infections (Ronald and Peeling 1993). The range of estimates of PID cases associated with chlamydia and gonorrhoea as reported in the literature is presented in Tables 9 and 10.

Although people with acute PID are often co-infected with *C. trachomatis* and *N. gonorrhoeae*, each of these pathogens has significant influence on the incidence of PID. Faulner and Soman (1991) estimate that only 10 percent of PID cases are non-venereal or iatrogenic in origin, whereas Rice and Schachter (1991) report that in 25-50 percent of PID cases there is no evidence of prior infection with either *C. trachomatis* or *N. gonorrhoeae*. However, Gjonnaess et al. (1982) report a 2.6-fold higher chance of PID with previous chlamydial or gonococcal infections. The range of estimates of PID cases that are caused by either *C. trachomatis* or *N. gonorrhoeae* is presented in Table 11.

**Table 9. Estimates of the Proportion of PID Cases Associated with Chlamydia**

Author	%
Bowie and Jones (1981)	51
Brunham (1983)	50
Bump and Fass (1985)	20, 40
Cates et al. (1990)	25-51
Chow et al. (1987)	55
Faulner and Soman (1991)	50
Gjonnaess et al. (1982)	50
Horsburgh et al. (1987)	25-50
Hughes et al. (1989)	20-66
Kristensen et al. (1985)	24
Mårdh (1980)	30, 62
Møller et al. (1981)	22
Mroczkowski (1990)	20-50, 22-47
Ronald and Peeling (1993)	30-66
Sanders et al. (1986)	24
Todd et al. (1988)	50
Washington et al. (1987b)	30-50
Washington et al. (1985a)	23-62, 22-47
Weström and Mårdh (1990)	38, 52, 60

**Table 10. Estimates of the Proportion of PID Cases Associated with *N. gonorrhoeae***

Author	%
Bowie and Jones (1981)	35
Brunham (1983)	5
Brunham et al. (1985)	40
Bump and Fass (1985)	0-65
Cates et al. (1990)	80
Chow et al. (1987)	10
Faulner and Soman (1991)	40
Horsburgh et al. (1987)	20-80
Kristensen et al. (1985)	13
Mårdh (1980)	44-65, 5-32, 25
Møller et al. (1981)	5
Mroczkowski (1990)	22-33
Rees (1980)	10-20
Ronald and Peeling (1993)	20-40
Sanders et al. (1986)	80
Spence et al. (1990)	31
Washington et al. (1987b)	39
Washington et al. (1985a)	38
Weström and Mårdh (1990)	44-70, 5-27

**Table 11. Estimates of the Proportion of PID Cases Caused by Either Chlamydia or Gonorrhoea**

Author	%
Aral et al. (1991)	26
Bowie and Jones (1981)	86
Canadian PID Society (1990)	75-85
Chow et al. (1987)	65
Kristensen et al. (1985)	37
Ronald and Peeling (1993)	80
Washington et al. (1985a)	62
Weström (1985)	75

The assumptions regarding the proportion of PID cases caused by chlamydia or gonorrhoea that we used for the cost analysis, based on the range of estimates reported in Tables 9-11, are presented in Table 12.

**Table 12. Proportion of PID Cases Caused by *C. trachomatis* or *N. gonorrhoeae***

	<i>C. trachomatis</i> %	<i>N. gonorrhoeae</i> %
Low estimate	25	20
Base estimate	50	30
High estimate	65	40

### **Hospitalization Costs**

PID is usually treated on an outpatient basis in Canada. Data from the HMRI and MEDECHO data bases indicate that there were 16 747 hospital separations for the primary diagnosis of pelvic inflammatory disease in Canada in 1989-1990. The average length of stay was 4.2 days. These separations were multiplied by the percentages in Table 12 to estimate the number of hospitalizations caused by *C. trachomatis* or *N. gonorrhoeae*. To estimate PID cases for the 15-24 (high-risk) age group, the proportion of total separations for this age group, 38 percent, was used.<sup>9</sup>

### **Outpatient Cases**

There are no reliable data on the number of PID cases treated on an outpatient basis in Canada. It has been estimated that there may be as many as 2-4 outpatient cases for each inpatient case of PID (Todd et al. 1988; Washington et al. 1987b; Cates et al. 1990; Banko 1989; Quan et al. 1983; Spence et al. 1990; Washington et al. 1986; Washington and Katz 1991). Using estimates of 3, 3.5, and 4 outpatient cases for each inpatient case for the low, base, and high estimates, respectively, the number of inpatient and outpatient cases of PID in Canada in 1989-1990 was estimated to be as follows:

	<b>Inpatient</b>	<b>Outpatient</b>	<b>Total</b>
Low (3:1)	16 747	50 241	66 988
Base (3.5:1)	16 747	58 615	75 362
High (4:1)	16 747	66 988	83 735

These outpatient cases were multiplied by the percentages in Table 12 to estimate the number of outpatient cases related to chlamydia or gonorrhoea.



### **Professional Billings**

It was assumed that a gynaecologist would be the primary physician treating PID. Gynaecologists' fees were calculated using an interprovincial comparison of gynaecologists' fee schedules for the major assessment (initial visit), daily hospital care visits, and other assessments (follow-up visits) (Canada, Health and Welfare Canada 1990). Since physicians' fees vary substantially across provinces, average low, base, and high gynaecologists' fees, weighted for utilization in each province, were estimated to be as follows:

	<b>Major assessment (\$)</b>	<b>Other assessment (\$)</b>	<b>Daily hospital visit (\$)</b>
Low	34.93	15.83	9.79
Base	42.49	18.24	13.83
High	49.42	21.24	18.59

For hospitalized PID cases it was assumed that there would be an initial general assessment, an assessment on admission to the hospital, a daily hospital care visit, and one follow-up visit after discharge from the hospital. For outpatient PID cases it was assumed that there would be an initial general assessment and one follow-up visit to the physician. Our estimates of physician visits are fairly consistent with those in other studies, which report an average of 2-2.5 physician visits for outpatient cases and 2.9-4 physician visits for inpatient cases (Washington et al. 1987b; Banko 1989; Washington et al. 1986; Washington and Katz 1991).

In addition to physician visits, a number of PID inpatients undergo diagnostic and surgical procedures that involve professional billing. These are estimated to range from 40 percent to 54 percent (Estany et al. 1989; Bump and Fass 1985; Banko 1989; Washington et al. 1986; Washington and Katz 1991; Russell and Love 1992); according to one analyst, 50 percent of this surgery is for hysterectomies (Bump and Fass 1985). For the present study, it was assumed that 50 percent of hospitalized PID cases underwent surgery and that of these, all had a laparoscopy and 50 percent a hysterectomy, and that the remaining 50 percent had major tubal repair surgery unrelated to hysterectomy.

To calculate professional billings related to laparoscopies, hysterectomies, and major tubal repair, the fees charged in Ontario were weighted by national surgical fees. In order to calculate surgeons', assistants', and anaesthetists' fees for diagnostic and surgical procedures in Ontario, assumptions are required regarding which day and time of day the procedure is performed, and the total time required. It was assumed that all procedures were performed on an elective basis, on weekdays, during regular hours of operation. The times estimated for these surgical procedures were

as follows: diagnostic laparoscopy (OHIP code Z552) — one-half hour; repair of extensive tubal disease for PID (OHIP code S743) — four hours; hysterectomy (OHIP code S757) — three hours (Ontario, Ministry of Health 1990b).

The professional fees for these procedures for Ontario were weighted by a national surgical fee index calculated using a comparison of provincial fee schedules for all surgical interventions (Canada, Health and Welfare Canada 1990). The following estimates of professional fees were assumed:

	Ontario (\$)	Canada		
		Low (\$)	Base (\$)	High (\$)
Diagnostic laparoscopy	253	196	236	277
Repair of extensive tubal disease	1 198	928	1 121	1 312
Hysterectomy	831	643	777	910

### **Drug Costs**

Based on Health and Welfare Canada guidelines, the treatment protocol assumed for inpatient and outpatient PID cases was Ceftriaxone 250mg IM, and Doxycycline 100mg BID to complete 14 days of treatment (Canada, Health and Welfare Canada 1988b).<sup>10</sup> Although other drug regimens are used, the combination of Ceftriaxone and Doxycycline is very common and has reported cure rates of 90-100 percent (Peterson et al. 1991). For costing purposes, medication expenses for hospitalized cases of PID were only included for treatment outside hospital, and a standard pharmacist's dispensing fee of \$8.50 was added to all outpatient prescriptions. Average drug costs were obtained from the Ontario drug benefit formulary (Ontario, Ministry of Health 1990a).

### **Productivity Losses**

For hospitalized cases of PID it was assumed that 20 days (including hospitalized days) would be lost from normal employment. For outpatient cases of PID it was assumed that 10 days would be lost (Todd et al. 1988; Washington et al. 1986).

### **Sequelae**

As shown in Figure 1, the most significant sequelae of PID for the reproductive health of women in Canada are tubal infertility, ectopic pregnancy, and chronic pelvic pain. According to some estimates, at least 25 percent of PID cases experience one of these sequelae following PID (Canadian PID Society 1990; Estany et al. 1989; Banko 1989). Studies have shown that the risk of ectopic pregnancy is 6 to 10 times higher in women with prior indication of PID, and chronic pelvic pain has been reported in 10-20 percent of PID cases (Canadian PID Society 1990; Ronald and Peeling 1993; Todd et al. 1988; Rivlin 1991; Mroczkowski 1990; Cates

et al. 1990; Banko 1989; Quan et al. 1983; Faulner and Soman 1991; Brunham 1983; Washington et al. 1985a; Russell and Love 1992; Hook and Holmes 1985; Weström 1975, 1980, 1985). The range of estimates of PID that results in tubal infertility as reported in the literature is presented in Table 13.

Although it has been estimated that, overall, 15-31 percent of PID cases develop tubal infertility, there is growing evidence that infertility following PID increases with the number of previous PID episodes. Presented in Table 14 are the estimates of tubal infertility following one, two, and three episodes of PID.

### Direct and Indirect Costs of Female Fertility Treatment

Infertility is usually defined as the lack of conception after one year of regular intercourse without contraceptives. Costs associated with treatment to correct for infertility are often overlooked in burden-of-illness studies of chlamydia, gonorrhoea, and PID. In the present study, fertility treatment costs were estimated by multiplying the number of infertility cases that were the result of chlamydia or gonorrhoea, the proportion of infertile cases who sought treatment, and the cost of the fertility treatment.

Determining the extent of infertility that is caused by chlamydia or gonorrhoea is problematic. The estimates of tubal infertility shown in Table 15 confirm reports that *C. trachomatis* leads to tubal infertility approximately three times more often than *N. gonorrhoeae* (Wasserheit 1987). However, since information on the total number of tubal infertility cases in Canada is not available, the approach used to estimate the proportion of tubal infertility cases following PID (see Table 14) was used for this analysis. It was assumed that 15 percent of patients were infertile after one episode of PID, 30 percent after two episodes, and 60 percent after three or more episodes. It was also assumed that 77 percent of all PID cases were first episodes, 17 percent were second episodes, and 6 percent were third or more episodes. The number of infertility cases due to either *C. trachomatis* or *N. gonorrhoeae* was calculated by multiplying these percentages by the number of inpatient and outpatient cases of PID caused by chlamydia or gonorrhoea. Since a large number of PID cases are "silent" and may go undiagnosed, the impact on the burden-of-illness estimates of an additional 30 percent and 50 percent of PID cases was investigated (Canadian PID Society 1990).

It was assumed that 25 percent of infertile couples sought medical care to correct their infertility. The impact on the burden-of-illness estimates of assuming that 10 percent and 50 percent of infertile couples sought medical care to correct for infertility was also investigated (Washington et al. 1987a; Hook and Holmes 1985). The estimates for 1990 based on the 25 percent assumption are presented in Table 16. For infertility in the 15-24 (high-risk) age group, the proportion of total

**Table 13. Estimates of the Proportion of Cases of PID That Develop Tubal Infertility**

Author	%
Brunham (1983)	15-20
Canadian PID Society (1990)	22
Curran (1980)	>20
Hughes et al. (1989)	17-21
Moore and Cates (1990)	17
Ronald and Peeling (1993)	20-31
Svensson et al. (1983)	17
Washington et al. (1986)	20
Washington et al. (1985a)	21
Wasserheit (1987)	20-25
Weström (1980)	20
Weström (1975)	21

**Table 14. Estimates of the Proportion of Cases of PID-Related Tubal Infertility Following One or More Episodes of PID**

Author	Following 1 episode (%)	Following 2 episodes (%)	Following 3 episodes (%)
Banko (1989)	15-25	n.a.	60
Brunham et al. (1985)	11	25	>50
Canadian PID Society (1990)	11-17	22-34	50-60
Cates et al. (1990)	11	<25	>50
Faulner and Soman (1991)	13	35	n.a.
Henry-Suchet (1988)	11	23	54
Hook and Holmes (1985)	15-20	n.a.	60
Mroczkowski (1990)	10	30	75
Quan et al. (1983)	13	36	75
Spence et al. (1990)	10	30	75
Ronald and Peeling (1993)	20	n.a.	>50
Todd et al. (1988)	17	n.a.	60
Wasserheit (1987)	10	25	>50
Weström and Mårdh (1990)	11	23	54
Weström (1975)	32	54	72



**Table 15. Estimates of the Proportion of Tubal Infertility Caused by *C. trachomatis* and *N. gonorrhoeae***

Author	Proportion of tubal infertility caused by chlamydia (%)	Proportion of tubal infertility caused by gonorrhoea (%)
Brunham et al. (1985)	64-91, 72	22
Miettinen et al. (1990)	40	14
Ronald and Peeling (1993)	40, 70	14

separations for ectopic pregnancies for this age group, 20 percent, was used.<sup>11</sup>

The estimates vary substantially, from 848 to 4 133 couples seeking medical care for chlamydia-related infertility and 678 to 2 543 seeking medical care for gonorrhoea-related infertility. This wide range is largely due to the etiology of tubal infertility (see Figure 1). Not only does tubal infertility have a number of causes other than STD, but these estimates are derived from the number of PID cases, which are in turn based on a range of estimates. Although the range of figures in Table 16 highlights the uncertainty of some of the estimates used in this analysis, it is quite likely that the true number lies within this range.

**Cost of Outpatient Treatment**

It was assumed that all couples who sought fertility treatment were treated on an outpatient basis. The results of a cost evaluation of the Chedoke-McMaster fertility clinic in Hamilton, Ontario, were used to determine which fertility treatments, on average, were used and the average cost of each (Goeree et al. 1993). Based on the results of a survey of 100 couples in a fertility program, the distribution of the fertility treatments undertaken is presented in Table 17.

Hospital clinic, laboratory, operating room, and short-stay unit costs for each type of fertility treatment were calculated based on average treatment protocols and using a simultaneous, fully allocated, hospital-costing model developed for Chedoke-McMaster hospital. Since this was a one-year burden-of-illness study and not a prospective patient follow-up study, it was assumed that each patient only received one cycle of each type of fertility treatment during 1990. A large proportion of total fertility treatment costs are associated with the initial screening and diagnostic work-up. Although the majority of fertility treatment costs have been included, it is likely that they are understated, because patients could undergo more than one treatment cycle in a year.

### **Professional Billings and Drug Costs**

Professional billings and drug costs for fertility treatment were estimated from a three-year follow-up study of 205 couples undergoing *in vitro* fertilization (IVF) and 194 couples receiving other fertility treatment, and from the average protocols of clinics and physicians. The Ontario Schedule of Benefits was used to estimate physicians' billings (Ontario, Ministry of Health 1990b). The costs of drugs consumed were obtained from average treatment protocols and from expense logs maintained by 40 of the couples undergoing IVF treatment and 40 of those undergoing other fertility treatment. Average drug costs were obtained from the Ontario drug benefit formulary (Ontario, Ministry of Health 1990a; Goeree et al. 1993).

### **Productivity Losses**

Productivity loss for fertility treatment was also based on the three-year follow-up study of the 40 couples undergoing IVF and the 40 undergoing other fertility treatment, who were asked to record time taken off work for fertility treatment (Goeree et al. 1993).

### **Sequelae**

There were approximately 4 172 hospital separations for the primary diagnosis of tubal infertility in Canada in 1989-1990, a portion of which were caused by STD pathogens. Because of the difficulty of attributing these separations to their etiological cause, we decided not to include these hospitalizations or other sequelae of tubal infertility in this analysis.

### **Direct and Indirect Costs of Ectopic Pregnancies**

An ectopic pregnancy is defined as a pregnancy where the fertilized egg implants itself on tissue outside the uterus or endometrial cavity, usually in the fallopian tube. Ectopic pregnancy is serious and accounts for approximately 5-12 percent of maternal deaths (Ronald and Peeling 1993; Chow et al. 1990). Ectopic pregnancy rates in Canada have steadily increased since 1975; there were 7 per 1 000 reported pregnancies in 1975, 9.3 per 1 000 in 1980, and over 16 per 1 000 in 1990.<sup>12</sup> This means that about 1 in 62 reported pregnancies in Canada results in an ectopic pregnancy. Known risk factors for ectopic pregnancy include age, previous pelvic infection, and the use of an IUD contraceptive. It has been estimated that prior pelvic infections account for the largest proportion (46-50 percent) of all ectopic pregnancies (Canadian PID Society 1990). Approximately 3-4 percent of PID cases have an ectopic pregnancy (Washington et al. 1987b; Washington and Katz 1991). Estimates of the proportion of ectopic pregnancies that are caused by prior PID infections as reported in the literature are presented in Table 18.

For costing purposes, it was assumed that 40 percent of all ectopic pregnancies were caused by prior PID infection for the low estimate, 50 percent for the base estimate, and 60 percent for the high estimate.

**Table 16. Estimates of the Number of Couples with Chlamydia- and Gonorrhoea-Related Infertility Seeking Medical Care, Canada, 1990**

	Ratio of outpatient to inpatient PID cases	Number of couples		
		Unadjusted for "silent" PID	Additional 30% for "silent" PID	Additional 50% for "silent" PID
<i>Chlamydia trachomatis</i>				
<i>Low estimate —</i>	3:1 (low)	848	1 102	1 272
25% of PID cases	3.5:1 (base)	954	1 240	1 431
due to chlamydia	4:1 (high)	1 060	1 378	1 590
<i>Baseline estimate —</i>	3:1 (low)	1 696	2 204	2 543
50% of PID cases	3.5:1 (base)	1 908	2 480	2 861
due to chlamydia	4:1 (high)	2 120	2 755	3 179
<i>High estimate —</i>	3:1 (low)	2 204	2 866	3 306
65% of PID cases	3.5:1 (base)	2 480	3 224	3 720
due to chlamydia	4:1 (high)	2 755	3 582	4 133
<i>Neisseria gonorrhoeae</i>				
<i>Low estimate —</i>	3:1 (low)	678	882	1 017
20% of PID cases	3.5:1 (base)	763	992	1 145
due to gonorrhoea	4:1 (high)	848	1 102	1 272
<i>Baseline estimate —</i>	3:1 (low)	1 017	1 323	1 526
30% of PID cases	3.5:1 (base)	1 145	1 488	1 717
due to gonorrhoea	4:1 (high)	1 272	1 653	1 908
<i>High estimate —</i>	3:1 (low)	1 357	1 763	2 035
40% of PID cases	3.5:1 (base)	1 526	1 984	2 289
due to gonorrhoea	4:1 (high)	1 696	2 204	2 543

**Table 17. Distribution of Fertility Treatments Received**

Type of treatment	%
Clomid® induction	31
Intrauterine insemination and Clomid® induction	6
Intrauterine insemination and Pergonal® induction	3
Intrauterine insemination	6
Therapeutic donor insemination	3
Tuboplasty	14
Lupron® therapy	3
<i>In vitro</i> fertilization (IVF)	34

**Table 18. Estimates of the Proportion of Ectopic Pregnancies That Are Caused by Prior PID Infection**

Author	%
Cates et al. (1990)	46-50
Miettinen et al. (1990)	40
Quan et al. (1983)	50
Ronald and Peeling (1993)	33, 19-95
Todd et al. (1988)	50
Washington and Katz (1991)	50
Washington et al. (1986)	50
Wasserheit (1987)	50
Wolner-Hanssen et al. (1990)	>50

### **Hospitalization Costs**

Almost all ectopic pregnancies involve a visit to an emergency department and an inpatient hospitalization (Banko 1989; Washington et al. 1987a). Data from the HMRI and MEDECHO data bases indicate that there were 7 317 hospital separations for ectopic pregnancies in Canada in 1989-1990.<sup>13</sup> The average length of stay was 4.8 days. For the cost analysis, these separations were multiplied by the percentages assumed to be due to PID (40, 50, and 60 percent) and by the estimates of PID cases due to either *C. trachomatis* or *N. gonorrhoeae* (see Table 12). For ectopic pregnancies among the 15-24 (high-risk) age group, the proportion of total separations for this age group, 20 percent, was used.



### **Professional Billings**

It was assumed that a gynaecologist would be the primary physician treating an ectopic pregnancy. Gynaecologists' fees were calculated using an interprovincial comparison of gynaecologists' fees for the major assessment (initial visit), daily hospital care visits, and other assessments (follow-up visits) (Canada, Health and Welfare Canada 1990). It was assumed that there would be an initial general assessment, an assessment on admission to the hospital, a daily hospital care visit, and one follow-up visit after discharge from the hospital (Washington et al. 1986; Washington and Katz 1991). To calculate professional billings related to the surgical management of ectopic pregnancy, it was assumed all procedures were done during weekdays and during regular hours of operation. The total time required for ectopic pregnancy management with tuboplasty (including prior diagnostic laparoscopy) was assumed to be 2.5 hours (OHIP codes E852 and E860) (Ontario, Ministry of Health 1990b).

The total professional fee for an ectopic pregnancy in Ontario was then weighted by the national surgical fee index (Canada, Health and Welfare Canada 1990). The professional fees assumed for an ectopic pregnancy were \$747 for Ontario, and \$578 (low), \$698 (base), and \$818 (high) for Canada.

### **Drug Costs**

Since all ectopic pregnancies are managed in the hospital and standard follow-up medication is not required (except analgesics where necessary), no additional drug costs were included for treatment out of hospital.

### **Productivity Losses**

Estimates of time taken off work due to ectopic pregnancies range from 15 to 28 to 39 days (Todd et al. 1988; Washington et al. 1986, 1987b). For the present analysis it was assumed that 28 days (including hospitalized days) of normal employment would be lost due to an ectopic pregnancy.

### **Sequelae**

Ronald and Peeling (1993) report that approximately one-third of women who have an ectopic pregnancy become infertile, one-third have normal term pregnancies, and one-third have miscarriages or repeat ectopic pregnancies. Since the number of ectopic pregnancies related to *C. trachomatis* and *N. gonorrhoeae* in Canada is so small and the potential number of infertility cases even smaller, the additional cases of infertility following ectopic pregnancy were not included in this analysis. Since some of the estimates of the proportion of women who became infertile following PID that were discussed earlier include infertility as a result of ectopic pregnancies, the direct omission of fertility treatment costs associated with ectopic pregnancies is likely to be negligible.

A greater potential concern for the burden-of-illness estimates for chlamydia or gonorrhoea is the risk of mortality as a result of ectopic

pregnancies. The mortality rate associated with ectopic pregnancy is approximately 1-1.8 percent (Ronald and Peeling 1993; Washington et al. 1987b). In 1989 two deaths because of ectopic pregnancy were reported in Canada (Canada, Statistics Canada 1991g). Because the number of deaths is small and since it was not possible to determine whether either was related to chlamydia or gonorrhoea, the burden of deaths associated with ectopic pregnancies was not included in the analysis.

## Direct and Indirect Costs of Chronic Pelvic Pain

Chronic pelvic pain has been defined as pelvic pain lasting longer than six months that causes the patient to seek medical advice from a physician. Approximately 10-20 percent of women with PID cases develop chronic pelvic pain (Canadian PID Society 1990; Ronald and Peeling 1993; Todd et al. 1988; Mroczkowski 1990; Quan et al. 1983; Faulner and Soman 1991; Brunham 1983; Russell and Love 1992; Weström 1975, 1980). Since little information is available on a national level for chronic pelvic pain and treatment regimens, the burden associated with chronic pelvic pain was not included in this analysis.

## Results

The burden-of-illness estimates for diagnostic and screening tests for chlamydia and gonorrhoea, and for male urethritis and epididymitis cases, uncomplicated female cervicitis and urethritis cases, PID cases, female infertility cases, and ectopic pregnancies due to chlamydia and gonorrhoea in Canada for 1990 are presented in Appendices A and B. They include low, base, and high estimates of hospital, physician, and productivity-loss costs and low, base, and high etiological estimates of the proportion of PID cases caused by the two pathogens. The overall range of burden-of-illness estimates for *C. trachomatis* and *N. gonorrhoeae*, by gender and high-risk age group, is presented in Tables 19 and 20. The higher overall burden-of-illness estimates for chlamydia are partly a reflection of its higher prevalence. Burden-of-illness estimates for *C. trachomatis* range from \$41 113 945 to \$123 060 598 for males and females combined, and those for *N. gonorrhoeae* range from \$29 624 272 to \$74 292 652 for males and females. The baseline, or best, estimate of the total cost of *C. trachomatis* and associated sequelae in Canada in 1990 is \$89 090 276, and the baseline estimate for *N. gonorrhoeae* and associated sequelae is \$54 011 873.

The majority of the total cost for males (74 percent for chlamydia and 87 percent for gonorrhoea) was for diagnostic and screening tests. However, as shown in Table 21, the majority of the total cost for females was for treating PID (54 percent for chlamydia and 61 percent for gonorrhoea). The total direct cost of PID for females ranged from

\$11 005 294 to \$35 776 493 for *C. trachomatis* and \$8 804 235 to \$22 016 303 for *N. gonorrhoeae*. The total indirect cost of PID for females ranged from zero dollars to \$28 393 403 for *C. trachomatis* and zero dollars to \$17 472 863 for *N. gonorrhoeae*. Overall, the impact of the sequelae of *C. trachomatis* and *N. gonorrhoeae* for females was significant, accounting for 72 percent and 82 percent, respectively, of total costs.

**Table 19. Burden-of-Illness Estimates for *C. trachomatis*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<i>Direct costs</i>			
Total females	36 218 605	57 544 105	77 869 976
15-24-year-old females	19 357 890	26 292 908	33 501 657
Total males	4 895 340	4 949 455	5 559 771
15-24-year-old males	2 817 883	2 849 033	3 200 346
<i>Indirect costs</i>			
Total females	0	25 239 619	36 919 084
15-24-year-old females	0	11 237 570	16 031 681
Total males	0	1 357 097	2 711 767
15-24-year-old males	0	485 551	970 232
<i>Total costs</i>			
Total females	36 218 605	82 783 724	114 789 060
15-24-year-old females	19 357 890	37 530 478	49 533 338
Total males	4 895 340	6 306 552	8 271 538
15-24-year-old males	2 817 883	3 334 584	4 170 578

## Discussion

This is the first burden-of-illness study of *C. trachomatis* and *N. gonorrhoeae* in Canada, and therefore our overall results cannot be compared with those of other studies. Three studies have, however, been conducted on PID, the most significant contributor to overall costs for females: the Canadian PID Society for the province of British Columbia in 1985 (1990), Banko for Ontario in 1989 (1989), and Todd et al. for Canada in 1985 (1988). Todd's estimate of the total direct cost of PID in Canada in 1985 is \$73 603 981. The estimate of the present study is approximately \$57 792 796. Comparing the two studies is confounded by differences between the costing methodologies used, but a large proportion of the difference between these estimates can be attributed to the reduction in the

**Table 20. Burden-of-illness Estimates for *N. gonorrhoeae*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<i>Direct costs</i>			
Total females	20 320 180	29 670 391	41 784 610
15-24-year-old females	9 215 330	12 172 322	16 102 609
Total males	9 304 092	9 344 855	9 907 827
15-24-year-old males	4 255 342	4 273 985	4 531 467
<i>Indirect costs</i>			
Total females	0	14 082 854	20 797 791
15-24-year-old females	0	6 151 563	8 794 554
Total males	0	913 773	1 802 424
15-24-year-old males	0	259 766	512 390
<i>Total costs</i>			
Total females	20 320 180	43 753 245	62 582 401
15-24-year-old females	9 215 330	18 323 885	24 897 163
Total males	9 304 092	10 258 628	11 710 251
15-24-year-old males	4 255 342	4 533 751	5 043 857

incidence of PID between 1985 and 1990 from 93 335 to 75 362 cases, a decrease of 19 percent (Canadian PID Society 1990; Banko 1989).

The significant burden of illness of *C. trachomatis* and *N. gonorrhoeae* suggests that these two pathogens are a major health concern for Canada. Of particular concern is the disproportionately higher estimates for the sexually active 15-24 age group, which accounts for 45 percent of the total burden-of-illness estimate for chlamydia and 42 percent of the estimated cost for gonorrhoea. Since the burden of PID and ectopic pregnancies that result from early infection with chlamydia or gonorrhoea actually occurs later in life, the true burden is underestimated in a cross-sectional prevalence-based burden-of-illness study.

Although the burden estimates for chlamydia and gonorrhoea are already significant, a number were not included here; for example, the pain and suffering associated with STD and PID infection, chronic pelvic pain, and ectopic pregnancies. In addition, approximately 5-15 percent of spontaneous abortions, stillbirths, premature labour, and neo-natal illness in Canada are due to STD pathogens (Ronald and Peeling 1993), and burden estimates associated with these sequelae have also not been included.



**Table 21. Distribution of Total Burden-of-Illness Cost Estimates for Females, 1990**

	<i>C. trachomatis</i> %	<i>N. gonorrhoeae</i> %
Diagnostic and screening tests	18	16
Female cervicitis and urethritis	10	2
PID	54	61
Tubal infertility	7	8
Ectopic pregnancies	11	13

A notable influence on the cost-of-illness estimates is the indirect cost, or productivity loss. Including productivity losses adds as much as \$39 630 851 to the chlamydia burden-of-illness estimates (33 percent of total) and \$22 600 215 to the gonorrhoea estimates (30 percent of total). More research is required to resolve the issue of whether productivity losses should be included in economic evaluations and burden-of-illness studies.

Another notable influence on the cost-of-illness estimates is the cost of diagnostic and screening tests for *C. trachomatis* and *N. gonorrhoeae*. As a percent of total costs, laboratory diagnostic and screening costs ranged from 15 to 45 percent for *C. trachomatis* and 21 to 53 percent for *N. gonorrhoeae*. The large influence of laboratory costs on the overall burden-of-illness estimates puts into question the method of extrapolating Ontario costs to the rest of Canada. Although the impact on the cost estimates of using national cost data could not be tested (because of the absence of these data), the significant influence of these costs emphasizes the importance and necessity of obtaining national cost data for future evaluations.

The wide range of estimates in this evaluation highlights the importance of sound epidemiological data on the etiology of the sequelae of chlamydia and gonorrhoea and of more accurate estimates of the cost of hospitals, physicians, drugs, and productivity losses. But obtaining more accurate information is problematic and exceedingly expensive. By providing a range of estimates, we have attempted to compensate for the inferior quality of the epidemiological and cost data; this also has the major advantage of increasing the probability that the true burden lies within the calculated range. The baseline, or best, burden-of-illness estimates should, however, be interpreted with caution. In addition, the total burden of both STD pathogens is not necessarily cumulative. Concomitant *C. trachomatis* and *N. gonorrhoeae* may be found in as many as 30 percent of women (Ronald and Peeling 1993).

It has been estimated that funding for STD and infertility research accounts for less than 1 percent of total funding for health research in

Canada (Ronald and Peeling 1993). In light of the fact that *C. trachomatis* and *N. gonorrhoeae* are preventable and treatable, the potential savings to Canada of more aggressive, targeted prevention programs could be enormous. These savings, however, must be carefully interpreted. Canada has seen a large decrease in the incidence of *N. gonorrhoeae* over the past decade. The change in incidence of *C. trachomatis* is not known, since it only became nationally notifiable in 1990. Knowing the national trends in the incidence of both these diseases is of pivotal importance in determining the long-term benefit to Canada of more aggressive research and prevention programs.

## Appendix A

**Table A1. Direct and Indirect Diagnostic and Screening Costs Caused by *C. trachomatis*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Laboratory</b>			
Total females	14 174 906	14 174 906	4 174 906
Total males	4 460 587	4 460 587	4 460 587
15-24-year-old females	9 958 511	9 958 511	9 958 511
15-24-year-old males	2 567 628	2 567 628	2 567 628
<b>Professional billings</b>			
Total females	124 743	158 789	399 997
Total males	39 254	49 968	125 872
15-24-year-old females	87 638	111 557	281 016
15-24-year-old males	22 596	28 763	72 455
<b>Productivity losses (Indirect costs)</b>			
Total females	0	202 197	404 393
Total males	0	127 799	255 598
15-24-year-old females	0	111 406	222 812
15-24-year-old males	0	45 725	91 449

**Table A2. Direct and Indirect Costs of Male Urethritis and Epididymitis Cases Caused by *C. trachomatis*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Hospitalization costs</b>			
Total males	8 197	8 674	9 249
15-24-year-old males	4 718	4 993	5 324
<b>Drug costs</b>			
Total males	230 098	230 098	460 226
15-24-year-old males	132 450	132 450	264 918
<b>Professional billings</b>			
Total males	157 204	200 128	503 837
15-24-year-old males	90 491	115 199	290 021
<b>Productivity losses (indirect costs)</b>			
Total males	0	1 229 298	2 456 169
15-24-year-old males	0	439 826	878 783

**Table A3. Direct and Indirect Costs of Uncomplicated Female Cervicitis and Urethritis Cases Caused by *C. trachomatis*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Hospitalization costs</b>			
Total females	4 587 982	4 855 299	5 177 483
15-24-year-old females	3 223 265	3 411 067	3 637 415
<b>Drug costs</b>			
Total females	706 514	706 514	1 429 112
15-24-year-old females	496 358	496 358	1 004 016
<b>Professional billings</b>			
Total females	599 611	774 047	1 792 066
15-24-year-old females	421 254	453 803	1 259 007
<b>Productivity losses (indirect costs)</b>			
Total females	0	2 104 240	3 721 813
15-24-year-old females	0	1 159 389	2 050 635

**Table A4. Direct and Indirect Costs of PID Cases Caused by *C. trachomatis*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Hospitalization costs</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	7 206 622	7 626 512	8 132 586
15-24-year-old females	2 738 516	2 898 075	3 090 383
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	14 413 244	15 253 025	16 265 172
15-24-year-old females	5 477 033	5 796 149	6 180 765
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	18 737 217	19 828 932	21 144 724
15-24-year-old females	7 120 142	7 534 994	8 034 995
<b>Drug costs</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	696 960	800 875	904 790
15-24-year-old females	264 845	304 333	343 820
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	1 393 920	1 601 750	1 809 580
15-24-year-old females	529 690	608 665	687 641
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	1 812 096	2 082 275	2 352 454
15-24-year-old females	688 596	791 265	893 933
<b>Professional billings</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	3 101 712	3 887 714	4 722 813
15-24-year-old females	1 178 651	1 477 331	1 794 669
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	6 203 425	7 775 427	9 445 627
15-24-year-old females	2 357 301	2 954 662	3 589 338
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	8 064 452	10 108 055	12 279 315
15-24-year-old females	3 064 492	3 841 061	4 666 140



**Table A4. (cont'd)**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Productivity losses (indirect costs)</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	0	10 010 495	10 920 540
15-24-year-old females	0	34 753 317	5 024 527
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	0	20 020 989	21 841 079
15-24-year-old females	0	9 506 633	10 049 054
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	0	26 027 286	28 393 403
15-24-year-old females	0	12 358 623	13 063 770

**Table A5. Direct and Indirect Costs of Treating Chlamydia-Related Infertility Among Women, Canada, 1990\***

	Low	Base	High
	(1990 Canadian dollars)		
<b>Clinic, laboratory and other hospital costs</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	1 507 062	1 695 445	1 883 828
15-24-year-old females	296 891	334 003	371 114
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	3 014 124	3 390 890	3 767 656
15-24-year-old females	593 783	668 005	742 228
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	3 918 362	4 408 157	4 897 952
15-24-year-old females	771 917	868 407	964 897
<b>Drug costs</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	62 971	70 843	78 714
15-24-year-old females	12 405	13 956	15 507
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	125 943	141 686	157 429
15-24-year-old females	24 811	27 912	31 013

**Table A5. (cont'd)**

	Low	Base	High
	(1990 Canadian dollars)		
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	163 726	184 191	204 657
15-24-year-old females	32 254	36 286	40 317
<b>Professional billings</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	958 096	1 077 858	1 197 620
15-24-year-old females	188 745	212 338	235 931
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	1 916 192	2 155 716	2 395 240
15-24-year-old females	377 490	424 676	471 862
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	2 491 050	2 802 431	3 113 812
15-24-year-old females	490 737	552 079	613 421
<b>Productivity losses (indirect costs)</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	0	120 122	133 469
15-24-year-old females	0	23 664	26 293
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	0	240 244	266 938
15-24-year-old females	0	47 328	52 587
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	0	312 317	347 019
15-24-year-old females	0	61 526	68 363

\* Based on assumption that 25 percent of PID cases result in tubal infertility.

**Table A6. Direct and Indirect Costs of Ectopic Pregnancies Caused by *C. trachomatis*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Hospitalization costs</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	1 867 839	2 367 206	2 938 629
15-24-year-old females	367 964	466 340	578 910
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	3 735 679	4 734 412	5 877 257
15-24-year-old females	735 929	932 679	1 157 820
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	4 856 383	6 154 735	7 640 435
15-24-year-old females	956 707	1 212 483	1 505 166
<b>Professional billings</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	623 587	910 822	1 255 024
15-24-year-old females	122 847	179 432	247 240
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	1 247 174	1 821 644	2 510 048
15-24-year-old females	245 693	358 864	494 480
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	1 621 326	2 368 138	3 263 063
15-24-year-old females	319 401	466 523	642 823
<b>Productivity loss (indirect costs)</b>			
<i>Low etiological estimate (25% PID due to C.t.)</i>			
Total females	0	1 335 974	1 558 637
15-24-year-old females	0	206 407	240 808
<i>Base etiological estimate (50% PID due to C.t.)</i>			
Total females	0	2 671 949	3 117 274
15-24-year-old females	0	412 814	481 616
<i>High etiological estimate (65% PID due to C.t.)</i>			
Total females	0	3 473 534	4 052 456
15-24-year-old females	0	536 658	626 101

## Appendix B

**Table B1. Direct and Indirect Diagnostic and Screening Costs Caused by *N. gonorrhoeae*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Laboratory costs</b>			
Total females	6 887 699	6 887 699	6 887 699
Total males	8 782 274	8 782 274	8 782 274
15-24-year-old females	4 663 832	4 663 832	4 663 832
15-24-year-old males	4 016 681	4 016 681	4 016 681
<b>Professional billings</b>			
Total females	20 195	25 707	64 758
Total males	25 751	32 779	82 571
15-24-year-old females	13 675	17 407	43 849
15-24-year-old males	11 777	14 992	37 765
<b>Productivity loss (indirect costs)</b>			
Total females	0	32 735	65 470
Total males	0	83 835	167 670
15-24-year-old females	0	17 384	34 767
15-24-year-old males	0	23 832	47 665

**Table B2. Direct and Indirect Costs of Male Urethritis and Epididymitis Cases Caused by *N. gonorrhoeae*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Hospitalization costs</b>			
Total males	84 343	89 258	95 180
15-24-year-old males	38 576	40 823	43 532
<b>Drug costs</b>			
Total males	306 796	306 796	613 914
15-24-year-old males	140 317	140 317	280 781
<b>Professional billings</b>			
Total males	104 928	133 748	333 888
15-24-year-old males	47 991	61 172	152 708
<b>Productivity loss (indirect costs)</b>			
Total males	0	829 938	1 634 754
15-24-year-old males	0	235 934	464 725



**Table B3. Direct and Indirect Costs of Uncomplicated Female Cervicitis and Urethritis Cases Caused by *N. gonorrhoeae*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Hospitalization costs</b>			
Total females	267 087	282 649	301 405
15-24-year-old females	180 851	191 389	204 089
<b>Drug costs</b>			
Total females	238 437	238 437	477 891
15-24-year-old females	161 452	161 452	323 592
<b>Professional billings</b>			
Total females	86 881	111 169	270 450
15-24-year-old females	58 829	75 275	183 128
<b>Productivity loss (indirect costs)</b>			
Total females	0	290 210	552 089
15-24-year-old females	0	154 114	293 182

**Table B4. Direct and Indirect Costs of PID Cases Caused by *N. gonorrhoeae*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Hospitalization costs</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	5 765 297	6 101 210	6 506 069
15-24-year-old females	2 190 813	2 318 460	2 472 306
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	8 647 946	9 151 815	9 759 103
15-24-year-old females	3 286 220	3 477 690	3 708 459
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	11 530 595	12 202 420	13 012 138
15-24-year-old females	4 381 626	4 636 919	4 944 612
<b>Drug costs</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	557 568	640 700	723 832
15-24-year-old females	211 876	243 466	275 056
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	836 352	961 050	1 085 748
15-24-year-old females	317 814	365 199	412 584

**Table B4. (cont'd)**

	Low	Base	High
	(1990 Canadian dollars)		
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	1 115 136	1 281 400	1 447 664
15-24-year-old females	423 752	486 932	550 112
<b>Professional billings</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	2 481 370	3 110 171	3 778 251
15-24-year-old females	942 921	1 181 865	1 435 735
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	3 722 055	4 665 256	5 667 376
15-24-year-old females	1 414 381	1 772 797	2 153 603
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	4 962 740	6 220 342	7 556 501
15-24-year-old females	1 885 841	2 363 730	2 871 471
<b>Productivity loss (Indirect costs)</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	0	8 008 396	8 736 432
15-24-year-old females	0	3 802 653	4 019 621
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	0	12 012 594	13 104 648
15-24-year-old females	0	5 703 980	6 029 432
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	0	16 016 792	17 472 863
15-24-year-old females	0	7 605 306	8 039 243

**Table B5. Direct and Indirect Costs of Treating Gonorrhoea-Related Infertility Among Women, Canada, 1990\***

	Low	Base	High
	(1990 Canadian dollars)		
<b>Clinic, laboratory, and other hospital costs</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	1 205 650	1 356 356	1 507 062
15-24-year-old females	237 513	267 202	296 891
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	1 808 475	2 034 534	2 260 593
15-24-year-old females	356 270	400 803	445 337
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	2 411 300	2 712 712	3 014 124
15-24-year-old females	475 026	534 404	593 783

**Table B5. (cont'd)**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Drug costs</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	50 377	56 674	62 971
15-24-year-old females	9 924	11 165	12 405
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	75 566	85 011	94 457
15-24-year-old females	14 886	16 747	18 608
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	100 754	113 349	125 943
15-24-year-old females	19 849	22 330	24 811
<b>Professional billings</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	766 477	862 287	958 096
15-24-year-old females	150 996	169 870	188 745
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	1 149 715	1 293 430	1 437 144
15-24-year-old females	226 494	254 806	283 117
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	1 532 954	1 724 573	1 916 192
15-24-year-old females	301 992	339 741	377 490
<b>Productivity loss (Indirect costs)</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	0	96 098	106 775
15-24-year-old females	0	18 931	21 035
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	0	144 146	160 163
15-24-year-old females	0	28 397	31 552
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total female	0	192 195	213 550
15-24-year-old females	0	37 862	42 069

\* Based on assumption that 25 percent of PID cases result in tubal infertility.

**Table B6. Direct and Indirect Costs of Ectopic Pregnancies Caused by *N. gonorrhoeae*, Canada, 1990**

	Low	Base	High
	(1990 Canadian dollars)		
<b>Hospitalization costs</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	1 893 765	1 494 272	2 350 903
15-24-year-old females	373 072	294 371	463 128
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	2 241 407	2 840 647	3 526 354
15-24-year-old females	441 557	559 607	694 692
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	2 988 543	3 787 529	4 701 806
15-24-year-old females	588 743	746 143	926 256
<b>Professional billings</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	498 870	728 658	1 004 019
15-24-year-old females	98 277	143 546	197 792
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	748 304	1 092 987	1 506 029
15-24-year-old females	147 416	215 318	296 688
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	997 739	1 457 315	2 008 039
15-24-year-old females	196 555	287 091	395 584
<b>Productivity loss (indirect costs)</b>			
<i>Low etiological estimate (20% PID due to N.g.)</i>			
Total females	0	1 068 780	1 246 910
15-24-year-old females	0	165 125	192 646
<i>Base etiological estimate (30% PID due to N.g.)</i>			
Total females	0	1 603 169	1 870 364
15-24-year-old females	0	247 688	288 970
<i>High etiological estimate (40% PID due to N.g.)</i>			
Total females	0	2 137 559	2 493 819
15-24-year-old females	0	330 251	385 293



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## Notes

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2. Unpublished data from Ontario Ministry of Health, Laboratory Licensing and Inspection Branch, Laboratory Services Branch, 1991.
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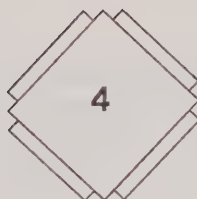
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# **Social Factors Relevant to Sexually Transmitted Diseases and to Strategies for Their Prevention: A Literature Review**

Louise Hanvey and  
Dianne Kinnon



## **Executive Summary**

Several trends in the transmission of sexually transmitted diseases (STDs), including the introduction of antibiotic-resistant diseases that may remain undetected for long periods of time, and the increasing number of adolescents of both sexes with a STD are reasons for concern. A growing number of Canadians are facing permanent infertility because of the increased spread of STDs.

The authors reviewed more than 200 journal articles, books, and theses published since 1975 to determine the major social factors involved in the transmission of STDs and to identify the strategies known to prevent the transmission of STDs.

The socioeconomic and sociodemographic factors examined included income, age, race, and the core group theory. The first section ends with a review of psychosocial factors and the roles played by gender in this area.

The prevention of STDs focusses on primary and secondary strategies — those aimed at either reducing risk factors for specific STDs

or enhancing the person's resistance to disease, and those designed to identify and treat diseases earlier than usual.

The authors discuss intervention models, efforts in public policy and community development, the role of education, experience in other countries, use of spermicides, factors influencing behaviour, social norms, and alcohol and drug abuse. They also examine programs that focus on acquired immunodeficiency syndrome (AIDS), clinic settings, school programs, and the instrumental part computers play in STD prevention education.

The section on secondary prevention includes detection, treatment, clinical care, parent counselling, and partner notification.

Overall, the material showed that a substantial amount of program development is under way in the field of STD prevention, that social factors are increasingly being considered in the design of prevention strategies, and that multi-faceted approaches that combine disease control and primary prevention are being used. However, work needs to be done in the research and program development areas to build on these trends and to address the spread of STDs in Canada.

## Introduction

Sexually transmitted diseases (STDs) are considered by many in the public health field to be a serious threat to the health of Canadians. The advent of acquired immunodeficiency syndrome (AIDS), by no means the most common disease but certainly that with the most severe consequences, has brought new attention to the whole array of communicable diseases that are transmitted by sexual contact. Several trends in the transmission of STDs, especially the introduction of antibiotic-resistant types, asymptomatic diseases that may remain undetected for longer periods of time, and a growing incidence among adolescent women and men, are causes for concern. For a growing number of Canadians, permanent infertility is the result of the increased spread of STDs. The more we are faced with the personal devastation felt by those who are infertile due to STDs, the social and economic consequences of treating reduced fertility, and the many other serious reproductive health conditions associated with these diseases, the more imperative prevention becomes.

How members of the public, policy makers, and health professionals regard STDs is changing, but our approach to these infectious diseases is still coloured by our values and perceptions about sexual promiscuity and individual responsibility for disease prevention. The challenge in addressing STDs as a public health issue lies in confronting our attitudes and values concerning the sexual nature of the diseases, re-examining traditional approaches to disease control, and acknowledging the need to understand the social context of individual health behaviour.

Historically, STD control has focussed on the health, or more specifically medical, factors associated with transmission of the diseases.

Increasingly apparent is that a wide range of health, social, psychological, and environmental factors play an important part in the spread of these communicable diseases. To develop effective prevention programs, it is critical to consider all of the factors involved; that is, social factors, environmental factors, and behavioural factors.

This literature review focusses on the following aspects of STDs: the nature of STDs and theories as to their transmission; the influence of various social factors; the examination of both the primary and secondary prevention strategies; and the exploration of specific prevention strategies — those that work and those that do not.

The relationships between social factors and the spread of disease are complex and certainly interrelated. This paper will address the following questions:

- What are the major social factors related to the transmission of STDs?
- How have these social factors been addressed in the design of prevention strategies?
- Which strategies have been effective in preventing STD transmission?
- What additional knowledge is required for the design of effective strategies?

The current published literature on social factors and the prevention of STDs provides few definitive answers to such questions. Much more research and thought is required to address these issues fully. This paper will provide a general overview of the extent and nature of the problem of STDs and their connection to infertility, highlight some of the major findings from the literature review, and present some comments on the limitations of our knowledge and need for further research.

In addition, the review will provide insights into the relationships between social factors and the spread of STDs and their ultimate contribution to prevention.

## **Purpose and Methodology**

The purpose of the literature review is twofold:

1. to determine the major social factors involved in the transmission of STDs; and
2. to identify the strategies known to prevent the transmission of STDs.

The social factors contributing to the spread of STDs and related prevention strategies will be examined in the English- and French-language literature published in the last 15 years in the following disciplines: health, psychology, sociology, mental health, education, and religious studies.



Specifically, 210 journal articles, books, and theses addressing the social factors in the transmission of STDs, and resulting prevention strategies, were reviewed. The information gathered in this study was limited to published materials and, as a result, does not capture current thinking that appears in the unpublished literature (program reports, research in progress, teaching materials, and discussion papers) or that exists among service providers and policy experts.

## Methodology

The literature review used a generalized search of published Canadian, European, and U.S. documents, and concentrated on Canadian materials for more extensive review. Computer-assisted searches were conducted in the following areas: MEDLINE (medical and nursing abstracts), PsycINFO (psychological abstracts), mental health abstracts, sociological abstracts, and Educational Resources Information Centre.

Manual searches were conducted in *Canadian Women's Periodical Index*, Canadian books and theses catalogued by the National Library of Canada, *Dissertation Abstracts International*, and the *Religion Index*.

Materials published from 1975 to the present were included. The keywords appropriate to each data base were used to identify articles relevant to prevention, social factors, sexually transmitted diseases (STD/venereal diseases), chlamydia, gonorrhoea, syphilis, and AIDS.

All documents were screened for appropriateness. The relevant articles were duplicated and reviewed in detail. Thirty-eight articles were read and subsequently excluded from the review paper because (1) they did not address prevention at either the primary or secondary level; or (2) they did not address social factors at any level. Forty-two articles did not arrive in time from inter-library loan to be included in the review.

Seven articles considering social factors related to STDs and their prevention were located in the *Canadian Women's Periodical Index*; five related to AIDS.

## Overview of the Literature

The literature is influenced heavily by U.S. studies. Of the 210 articles, 28 described Canadian work, 14 British, 11 European and other. The remainder described U.S. work. It is difficult to reach any conclusions about the prevention strategies in countries other than the United States because of the limited amount of information. Reference is made throughout the paper to specific countries where it is appropriate.

The Canadian literature focusses primarily on education strategies and AIDS. One Canadian report of significance is the *Canada Youth and AIDS Study* (King et al. 1988), which examined social factors relating to adolescents revealed from the results of that study. Little else was found that examined other social factors within Canadian society, or which looked

at the sociodemographic and socioeconomic factors in Canadian society that would influence STDs.

A review of French-language literature revealed six references. One described the services in Quebec, particularly the Montreal region. One reported on a survey of youth in Switzerland, and the others were descriptive articles focussed particularly on education. The relevant articles are cited throughout the text.

The literature focussed largely on biomedical factors rather than on social factors. Most of the literature related to the epidemiological or medical models of STD control, as opposed to consideration of behavioural or social factors that contribute to transmission and prevention.

There is less research-based literature than historical or exhortative reports. Some randomized controlled trials are reported, most of which test educational interventions. Little of the experimental literature assessed social and behavioural influences.

Most of the literature on prevention focussed on education. Approximately 60 of the 210 articles focussed on education alone. Of these, 17 attempted to evaluate educational interventions; 11 used an experimental design. More than half of the remaining articles included education as a strategy.

In the assessment of prevention strategies, most emphasis has been on individual behaviour, rather than on social structures and group influence. Prevention activities in the primary-care setting were the most often reported, except for AIDS, where social marketing and mass education programs have been more prevalent. Most research into clinical care and practice patterns was in STD clinic settings, not in private caregiver settings.

From 1986 onward, nearly two-thirds of the literature related to human immunodeficiency virus (HIV)/AIDS prevention and transmission. Of 123 articles reviewed from 1986 onward, 78 were related specifically to HIV/AIDS; 45 were not.

## Overview of the Report

The literature review begins with an examination of the social factors that influence STDs. They are grouped according to socioeconomic, sociodemographic, and psychosocial factors. The second part of the review explores the prevention of STDs. The prevention literature is described in terms of three models — medical, epidemiological, and sociological. The paper concludes with a description of the education strategies that are reported in the literature.

## Social Factors and STDs

### Definitions

The literature described a wide variety of social factors that could influence the incidence and transmission of STDs. For this review three broad categories have been identified.

Socioeconomic factors are those that describe a person's position in society according to educational level attained, income, occupation, and the value of the person's dwelling (Last 1988).

Sociodemographic factors are those that describe certain personal characteristics, such as age, sex, marital status, place of birth, ethnic origin, and residence (Personal Communication with R. Wilkins of Statistics Canada, 1991).

Psychosocial factors are those that directly affect behaviour, and the context of that behaviour, such as attitudes, values, culture, and beliefs. (The sociological and psychological literature made frequent reference to "psychosocial factors," but no consistent, clear definition was presented; therefore, this definition is a synthesis of the literature findings.)

## Socioeconomic and Sociodemographic Factors

### *Income*

Cates and Toomey (1990), Aral and Holmes (1991), Potterat et al. (1985), Rothenberg (1983), and Peck (1986) all associated low socioeconomic status, specifically low income, with high rates of STDs in the United States. Bell and Holmes (1984), after studying American youth, associated low socioeconomic status with both early coitus and increased risk of acquiring STD. They concluded that the lower socioeconomic status of females, who may begin sexual activity at a young age, contributes to their higher rates of STDs.

In contrast, in Britain, Fulford et al. (1983a, 1983b) found that the overall occurrence rates of STDs had no etiologically relevant association with social class or occupation. (Their study population was 1 000 men attending a STD clinic in London, England.)

In Australia, Murrell and Pamnany (1981) compared random samples of men with non-gonococcal urethritis ( $n = 239$ ) with men suffering from gonorrhoea ( $n = 230$ ). They found that the men in the former group had a higher socioeconomic status, lower incidence of casual partners, and less frequent homosexual activity.

No comparable Canadian literature described the socioeconomic status of the populations with STDs in Canadian society.



## Age

The research also concluded that STDs are especially prevalent among young women. Sexually active young people are seen to be at risk of contracting STDs because they generally engage in high-risk behaviours; often have more than one sexual partner; combine sexual encounters with drug and alcohol use (further reducing the probability of preventive behaviour); lack the skills and assurance to negotiate safe sex choices with their partners; and are resistant to the use of condoms (Hacker 1989; Becker and Joseph 1988; O'Reilly and Aral 1985; and Kegeles et al. 1988, among others).

That young people are a significant group at risk of transmitting STDs is borne out by the epidemiological data (King et al. 1988). In Canada in 1988, females between 15 and 19 years of age had the highest reported rate of gonorrhoea (357.5 per 100 000), exceeding that for males from 20 to 24 years of age (345.2 per 100 000) (MacDonald et al. 1990). Survey results of sexually active Canadian adolescents and young university women reveal *Chlamydia trachomatis* infection rates of 5 percent to 20 percent (Bowie et al. 1981). For example, Hughes et al. (1989) screened 541 sexually active adolescent girls attending a paediatric gynaecology clinic in an Ontario children's hospital over a one-year period; they found a chlamydia rate of 14.7 percent. Shafer et al. (1984) screened all sexually active adolescent girls 13 to 21 years of age who had a pelvic examination at a hospital teen clinic in a large U.S. urban centre (n = 366). The incidence of chlamydia endocervical infection was 15.3 percent, with a rate of 23.3 percent for Blacks, 14.3 percent for Hispanics, and 10.3 percent for whites. Oral contraceptive users had a higher rate of infection (23.8 percent) than those using a barrier method (16.2 percent).

Epidemiologists saw the first social niche occupied by AIDS as homosexual and bisexual men; drug users are the second. The third social niche is postulated to be young, sexually active adolescents who are experimenting with drugs (Hacker 1989). Young people everywhere are seen to engage in high-risk behaviours (Becker and Joseph 1988). One survey study (O'Reilly and Aral 1985) supported the notion that adolescents are an important component of the population at risk for STDs.

The *Canada Youth and AIDS Study*, the most extensive study of adolescent sexual behaviour and beliefs related to AIDS, indicated that Canadian youth were at high risk of acquiring a STD, and that their knowledge concerning STDs was unrelated to safe sex practices. In all, 5 514 students in first-year community college and university classrooms across Canada were surveyed to assess STD/HIV-related knowledge, attitudes, and risk behaviour. The results showed that most students know what types of sexual activity increase the risk of HIV transmission, but many still engage in risky behaviour (MacDonald et al. 1990).

Strunin and Hingson (1987) reported that 70 percent of adolescents in their sample were sexually active, but only 15 percent acknowledged any change in sexual behaviour due to the danger of contracting AIDS. Of



those reporting a behaviour change, only 20 percent used effective prevention methods.

Aral and Holmes (1991) explained the increased incidence in STDs by the demographic shifts in society. When childhood mortality decreases, but birth rate does not, an increased number of adolescents and young adults precede the increase in the number of adults; this is seen as a slowly ascending bulge in the age pyramid. Because STDs are concentrated among teens and young adults, these infectious diseases can be expected to increase in incidence as the population bulge passes through these ages. As well, when the number of young people is disproportionately large, they may be influenced less by the social norms of the older generation; therefore, more may engage in behaviours that increase their STD risks.

Cates et al. (1990) reported that considerably higher ratios of chlamydia/gonorrhoea were found among American whites, pregnant women, users of oral contraceptives, and asymptomatic people. (They also reported that nearly all studies have found that use of oral contraceptives was associated with increased risk of lower genital tract chlamydia infection.) Other variables identified as risk factors for STDs include both a younger age at first intercourse and more years of sexual activity (Shafer et al. 1984).

### **Race**

The literature from the United States shows that Black and Hispanic Americans are at much higher risk of having STDs than white Americans (Aral and Holmes 1991; Cates and Toomey 1990; Potterat et al. 1985; Henderson 1977; Rothenberg 1983; Peck 1986; and Aral et al. 1986). (Most authors stated that race, other sociodemographic factors such as urban living and young age, and socioeconomic factors, such as income, are all contributing factors to STDs.)

Aral and Holmes (1991) reported that in the United States, racial differences between Blacks and whites in the incidence of gonorrhoea have widened sharply since 1984. However, they noted there might be some under-reporting for whites, since they rely more on personal physicians and private clinics, which tend to under-report gonorrhoea. The same difference occurs for syphilis. The authors also reported that chlamydia occurs in all ethnic and racial groups and all socioeconomic classes. Young women and women using oral contraceptives were considered to be more susceptible to chlamydia infection if exposed. Asymptomatic chlamydia is more common than asymptomatic gonorrhoea. Aral and Holmes attributed the high proportion of STDs in Black and Hispanic populations in part to demographic trends. These populations have age pyramids similar to those of developing countries, with large numbers of teens and young adults and fewer older adults. In the white population, however, the number of younger age groups is declining.

### ***Combination of Factors***

Cates and Toomey (1990) described that, in the 1980s, public perceptions of the risks of acquiring AIDS and herpes apparently led some Americans to change their sexual practices to reduce exposure to STDs. These behavioural changes have measurably influenced STD rates and patterns of transmission among homosexual men, but less impact has been observed in teenage and low-income, inner-city, and minority heterosexual populations.

Cates and Toomey claimed further that STDs have received prominence because of an interaction between sociodemographic factors and disease-related factors. They stated that the size of the population at risk has risen; the composition of the STD core population has changed; the incidence of the newer STDs has increased; STDs have been associated with incurable and fatal conditions; the key impact of STDs on maternal and child health is now apparent; international travel has led to the spread of STDs, making them a global problem; and many STDs appear to facilitate acquisition and expression of other diseases.

(No articles were found that described STDs in Canada as they related to specific racial or ethnic groups.)

### ***Problems with Data***

Cates et al. (1990) claimed that data on reportable diseases have many limitations and need to be interpreted with caution for the following reasons: there are differences in the completeness of reporting between public and private health care sources; national surveys are sporadic and based on self-reported information; and data from private physician practices are affected by the absence of standard diagnostic procedures, while data from STD clinics or health facilities experience problems of patient selection bias and geographic differences.

Peck (1986) stated that the increase in STDs among the general population and among teenagers in particular is a justifiable concern, but that the current state of knowledge based on models of populations at risk to STDs is questionable. The absence of certain kinds of information in official records, and the lack of data pertaining to interpersonal and intrapersonal motivation serve as a reminder that official data are insufficient for testing existing risk models. He gathered data from patient records ( $n = 763$ ) generated during a one-year period in a "social hygiene" clinic. Patients received free diagnostic and treatment services related to a variety of sexually transmitted infections. It was hypothesized that patients infected with gonorrhoea were young, poor, Black, housewives, bisexual, or homosexual. The investigation, however, was limited by a sample comprising a group of patients treated at a single facility, who were not randomly selected. The kinds of data that were available in the clinical records also presented measurement problems. The findings raised several issues with regard to public health models of populations at risk for STDs.

Peck affirmed that the information from available data inhibits empirical evaluation of the STD problem. He contended that, even if there has been a change in the relationship of the communicable diseases to human sexuality, the behaviour involved has not changed. What has changed is a public reaction to the problem. The fact that a large portion of the population has become infected with STDs does not confirm that they are more or any less promiscuous than members of previous generations.

Sisk et al. (1988) confirmed this by stating that the data are poor on sexual behaviour in the overall population and that a U.S. survey of adult sexual behaviour was being conducted. This type of meaningful baseline information is needed to develop programs.

## Core Group Theory

The core group theory put forth the thesis that STDs are concentrated within specific core groups of the population which are sociodemographically and geographically defined. Within these core groups the rate of transmission of STDs is high enough to sustain the infection within the population: on average, every infected person infects at least one other person. It is postulated that preventing or curing a STD in a member of a core group has much more impact than directing prevention strategies to people who are unlikely to transmit the infection.

There are, however, differences in opinion over who the core groups are and the degree to which they contribute to the transmission of various STDs. All of the literature on core group theory is American-based; no similar discussion or exploration of this theory appears in the Canadian literature.

The core group theory has implications for prevention programs aimed at specific populations. Aral and Holmes (1991), in their review of social factors contributing to the transmission of STDs, observed that the steady decrease in the incidence of gonorrhoea and syphilis among adult white heterosexuals in the United States and other countries is consistent with the implementation of effective public health control measures. However, bacterial STDs have re-emerged in young, Black, and Hispanic inner-city poor populations, as have AIDS and other viral STDs. Thus, they hypothesized that STDs have concentrated within specific high-risk heterosexual populations and population subgroups — the so-called core groups of frequent transmitters for these diseases.

Potterat et al. (1985) studied all people with culture-documented gonococcal infection in Colorado Springs, Utah, in a six-month period in 1981. They concluded gonorrhoea occurs in small, socially definable segments of the population (1 306 out of 127 154 residents aged 15 to 34, or 1 percent). The individuals tended to be young, non-white, of lower socioeconomic status, heterosexual, and connected to the military. They lived close to each other and socialized together. As a result of these findings, the authors disputed the popular concept that the risk of



acquisition of STDs is uniform, random, and directly related to "promiscuity." They stressed the importance of investigations of STDs focussing on measures of social situations as opposed to individual transaction.

Henderson (1977) suggested that gonorrhoea transmission can be attributed to a relatively small number of infected people who have many partners — a core group of infected persons, including asymptomatic women, homosexuals, and bisexuals, is responsible for the STDs within the core group. The model specifies that this core group lacks responsibility. Henderson suggests that the STD transmission frequency can be attributed to those who may know about their STD but who are unlikely to seek medical attention, and yet continue to have sexual relations.

Rothenberg (1983) studied the patterns of reported gonorrhoea in upstate New York (exclusive of New York City) from 1975 to 1980 and found the disease to be concentrated in urban areas, with diminishing incidence in the rural areas. The relative risk for gonorrhoea in these central core areas, compared to background state rates, is 19.8 for men and 15.9 for women, but as high as 40 in selected urban census tracts. These core areas are characterized by high population density and low socioeconomic status. Contact investigation data suggested that sexual contacts tend to live in close proximity. The author concluded that epidemiological resources should be focussed on as a major disease control strategy.

Aral and Holmes (1991) reported that a public health focus on the determinants of STDs in individual cases, and prevention approaches that identify persons most at risk, are most appropriate when exposure to the cause of a disease is heterogeneous in the population. American society is marked by increasing similarities within social groups and a widening gap between them. The formation of a growing underclass reflects these tendencies. Social problems such as lack of education, joblessness, homelessness, welfare dependency, family dissolution, drug abuse, homicide, and other crimes are concentrated in inner-city neighbourhoods. STDs and many other health problems follow this pattern.

The authors concluded that although the incidence rates and morbidity rates for many STDs differ greatly among socioeconomic, demographic, and behavioural subgroups, within these subgroups the risk factors that determine what causes individual cases of STDs may be far less important than the overriding social forces that affect the group. Consequently, they contended that the strategies for preventing STDs should target not only susceptible high-risk people but also entire communities and subgroups with high STD rates. Such strategies, ranging from improved birth control services to better educational and job opportunities, should address the full scope of factors underlying the high rates.

All of the authors cited previously described the core groups with regard to their demographic, socioeconomic, and behavioural characteristics, but none of the cited authors investigated the motivation behind the



groups' behaviours, or the social norms influencing these outcomes, although Birch and Stoddart (1990) attempted to extend the application of economic analysis to the determinants of individual behaviour. They present the view that behaviour is based on an individual's assessment of *personal* gains and losses from that behaviour, rather than "the social good."

## Psychosocial Factors

In an article written by W.W. Darrow, "Social and Psychologic Aspects of the Sexually Transmitted Diseases: A Different View," the following comment was made: "Most Americans believe that the venereal disease problem in [their] country is a medical problem with some behavioural aspects. I believe that the problem is essentially social, with some very important medical aspects" (1981, 307).

However, the literature contains a great deal of controversy over which psychosocial factors contribute to the transmission of STDs, and conflicting information regarding the populations most at risk.

In the early 1970s, Millar (1971) asserted that several reasons exist for the unsuccessful efforts of public health officials to control STDs. Identifying several social and cultural characteristics involved, Millar suggested that the problem of STDs could be attributed to the fact that the target populations at risk are the least influential members of society, which include poor Blacks, homosexuals, and teenagers. Confounding this is the persistent negative attitudes of affluent members of the community toward STDs (Peck 1986). Darrow (1975) attempted to test empirically the Three P Model based on the assumption that permissiveness, promiscuity, and the pill are major variables contributing to the transmission of STDs. Darrow conceptualized the problem as a result of sexual attitudes that have become more permissive; sexual behaviours that have become more promiscuous; and technological advances in contraception that have contributed to permissiveness, promiscuity and, in turn, the epidemic of STDs. Darrow's analysis relied on some clinical information, but is based primarily on national statistics and a sexual relationship survey of college-age people. He concluded that these kinds of data preclude a direct test of the assumptions upon which the Three P Model is based. Using only clinical data, it is difficult to confirm that infected patients engage in indiscriminate, brief, and random sexual relationships. In addition, aggregate data have no utility for assessing permissive attitudes. Without the use of a permissiveness scale, the hypothesized relation between permissiveness and the spread of STDs cannot be tested. Finally, self-reported patterns of contraceptive use are not an adequate measure of promiscuity. The availability of oral contraceptives per se does not promote promiscuity. The report disputed the belief that permissiveness, promiscuity, and the availability of oral contraceptives contribute to the spread of STDs.

Regarding public attitude toward STDs acting as a deterrent to the progress in controlling these diseases, Henderson (1977, 215) stated:

Although this attitude is changing, the reaction of most persons who learn for the first time that they have syphilis or gonorrhoea remains one of shame. Emotionally, these are not perceived as communicable diseases so much as evidence of moral wrong doing. The stigma is powerful, and related to general attitudes toward sexuality.

Although public attitudes are important when discussing STD control, of equal importance are the attitudes of public health officials. The perceived stigma and concomitant shame experienced by patients, not permissiveness or promiscuity, may be the greatest impediment to progress in the control of these diseases.

Peck (1986) further stated that limited progress can be expected in the current efforts to curb the STD problem if its victims continue to be defined as promiscuous. Social myths surrounding the victims of STDs abound, particularly that infected people tend to have "promiscuous" sexual lifestyles. Peck found that patients in the STD clinic suffered anxiety and low self-esteem and that the public holds an overall negative view of STDs — a resultant social stigma is attached to being a carrier.

The author concluded that STDs are not exclusively a malady of "social degenerates" or "promiscuous" individuals. STDs affect people of all age groups and social standing. This knowledge has the potential to enlighten policy makers and to be a basis for creative strategies to deal with the STD problem. A more realistic attitude among health professionals toward persons infected with STDs would be helpful also. Official interpretations endorse the supposed relationship between a new sexual liberty and increases in STDs. The public is advised that STDs are an outgrowth of this new sexual licence, but little evidence directly shows this relationship.

Fulford et al. (1983a, 1983b) used a standardized questionnaire to examine the possible contributions of "delinquent" and other "abnormal" personality traits, "disturbed attitudes to sex," and all psychiatric disorders to the risk of STD infection in men attending a STD clinic. The clinic group was matched with a control group. Although an association between delinquency and STD has been widely assumed, the results of the study did not suggest an excess of psychiatric disorder in the clinic patients.

Aral and Holmes (1991) reviewed the social factors contributing to the transmission of STDs in the United States. They observed that poor inner-city minority populations of industrialized countries resemble populations of developing countries. They have rapid demographic changes, with highly mobile populations. The sale of drugs has suddenly put large sums of money into the daily life of inner-city communities, often through young adolescents, thus radically altering the social structure. Similarly, frequent violence in the inner cities of the United States points to the tentative nature of power hierarchies in those communities. The swift demographic,

economic, and political changes in these populations result in a social situation in which levels of transience and marginality are high. Such conditions reinforce behaviour based on socioeconomic inequality, such as prostitution and illegal drug use, to become adaptive responses that help people acquire money, power, or pleasure that would be unattainable otherwise. These activities can enhance the spread of STDs.

## Gender and Psychosocial Factors

There is an appalling lack of analysis of psychosocial factors related to the transmission of STDs by gender. Most references to gender related to attendance at STD clinics and to behaviour related to condom use. Statements such as "women should be more assertive in sexual relationships" and "educational programs should include skill-building exercises for women to enable them to convince their partners to wear condoms" were found in the literature. Virtually no reference was made to power and status of women in society, and their effect on STDs. The few references in the literature were related to developing countries.

Baldwin et al. (1990) found that women engaged in safer sexual practices more often than men. This may be because women receive more education about health, safety, and social concern than men, and imprudent sexual activities can cause serious problems for women. In addition, they often learn from their mothers, peers, or personal experiences to be more cautious about sex than men tend to be. The authors concluded that if heterosexual men obtained more of the type of socialization that women typically receive, with an emphasis on health, safety, and social concern, both sexes might benefit.

Sexist and moralistic assumptions are prevalent in the treatment and prevention of STDs. Barnett (1985) reported that the media are increasingly promoting the idea that sexual activity should be restricted to one partner. Historically, in North America, it has been a socially accepted belief that men, not women, would have more than one sexual partner, and that "fallen women" and prostitutes were responsible for "giving" STD infections to men. Barnett also argued that STDs are being used to blame women for risks to their unborn babies.

## Prevention of STDs

### Overview

Prevention strategies are commonly grouped into three categories. Primary prevention strategies are aimed at either reducing risk factors for specific STDs or enhancing the person's resistance to the diseases. Secondary prevention involves strategies designed to identify and treat the diseases earlier than usual. Tertiary prevention strategies are aimed at



reducing the consequences of the disease once it is established. Health promotion is the process of enabling people to increase control over, and to improve, their health. To reach a state of complete physical, mental, and social well-being, an individual or group must be able to identify and to realize aspirations, to satisfy needs, and to change or cope with the environment; thus, health is seen as a resource for everyday life, not the objective of living. Health promotion strategies and actions include building healthy public policy, creating supportive environments, strengthening community action, developing personal skills, and reorienting health services (International Conference on Health Promotion 1987).

Historically, the most common approaches to preventing STDs found in the literature are secondary prevention measures — detection and treatment. Recently, the literature has been moving toward primary prevention, particularly in response to HIV and AIDS. The most common approach to primary prevention of STDs is education. A significant amount of literature exhorted educational efforts (mostly directed at HIV prevention), but less critically evaluated such interventions. Little in the literature moved from secondary through primary prevention to health promotion, and looked at social and public policy issues.

## Models

Approaches to intervention in the transmission of STDs can be grouped into three models: the medical model of disease prevention which relies on health care professionals (primarily physicians) to define, remedy, and control the problem in a passive patient; the epidemiological model which bases its understanding of disease on three major factors — hosts, agents, and the environment; and the sociological model which attempts to look at the whole environment in which STDs are transmitted, including societal structures and values. Darrow (1981) supported the latter argument.

Some intervention models provide the framework for prevention and control of STDs. Strategies most often found in the literature, however, were those based on the medical model or the epidemiological model.

The medical model embraces the essential components of secondary prevention. This involves accurate reporting of STD cases, early diagnosis and effective treatment, finding and treating sexual contacts of infected persons (also called contact tracing or partner notification), and screening (testing all individuals in a defined population) high-risk groups for STDs (Sherris and Fox 1983; Cates and Toomey 1990; Adler 1984; Montesinos et al. 1990; Centers for Disease Control 1990). In addition, some authors described models that combine primary prevention — for the most part composed of education — with secondary prevention in the form of screening, diagnosis, treatment, and research.

The epidemiological model consists of three major components: the host, or the person who is susceptible to the disease; the infectious agent,



or the cause of the disease; and the environment, or the circumstances surrounding the transmission of the disease. The three essential ingredients are interactive. STDs are considered to be the consequences of delicately balanced interactions among hosts, agents, and environments over time, and are to be prevented, controlled, and eradicated by intervening in these natural processes. The interventions include preventive actions, changing environmental conditions, and clinical medicine. This model is fundamental to the policies and programs for communicable disease control (Lilienfeld and Lilienfeld 1980).

Darrow (1981) proposed a sociological model that includes health consumers and health care providers as equals in a dynamic process of interaction, communication, and exchange. In this model, the environment expands to include social and cultural dimensions, in addition to geographic and political boundaries. It requires that professionals examine their own values, attitudes, and behavioural patterns, as well as those of the people they are trying to serve.

Using this model, Darrow described some shortcomings of U.S. providers that currently exist in the response to STDs. He found that only 2.6 percent of all private physicians doing pelvic examinations in the United States took endocervical specimens for Thayer-Martin cultures; 40 percent of women tested for gonorrhoea were not given the most sensitive test available; 29 percent of patients diagnosed with STDs were inappropriately treated and close to 35 percent received inadequate doses of drugs; and physicians only reported 10 percent of all cases of gonorrhoea they diagnosed. Darrow asserted that health professionals must take a critical look at their own values and behaviour, and that of the patient community as well.

Several writers pointed to environmental barriers to the prevention of STDs that fit well with the sociological model. Comprehensive, multi-faceted prevention strategies are advocated. Sherris and Fox (1983) stated that political support affects the implementation of prevention programs aimed at STDs. Such support is often difficult to achieve. Secondly, such programs compete for funding with efforts to prevent or treat serious endemic diseases that affect the entire population. Thirdly, prevention programs require knowledge of which conditions or diseases are most prevalent — information not always available.

Aral and Holmes (1991) concluded that in the 1990s, the solution to the STD crisis cannot rest solely with preventing high-risk behaviours in individuals. The factors that determine the high incidence of AIDS and other STDs in specific groups and in entire communities must also be identified and addressed. A balanced public health STD program must include expanded clinical and health education services. Clinical services for STD control should grow to meet the demand, integrate with family-planning and related programs, and adopt the technological advances of the past decades in STD prevention and control. Prevention activities ought to include population and group approaches and individual counselling. By

themselves, the medical solutions to the prevention and control of STDs are not enough; they must be coupled with the identification and correction of the societal factors responsible.

## **Efforts in Public Policy and Community Development**

Although little in the literature described public policy approaches to STD prevention, the few references that exist point to successful and unsuccessful approaches. Problematic approaches to policy development and structures include fragmented efforts, a hostile political environment, poor coordination of prevention and control services, inadequate funding for programs, lack of training in medical schools, and lack of evaluation of educational services (Walters 1989; Adrien and Carsley 1986).

In Canada, the Federal AIDS Strategy is an example of a public policy and empowerment of community approach to AIDS prevention (Clayton and Meltzer 1989). The federal AIDS program was orchestrated by the Federal Centre for AIDS, created in 1987. The Centre was made up of six bureaus, including the Program Analysis and Resources Bureau, which is the focal point for policy and program development, and the AIDS Prevention and Services Program, which focussed on education, liaison with health care workers and community groups, and the psychosocial aspects of the epidemic. In early 1992 the Centre was disbanded, with responsibilities turned over to various programs within Health and Welfare Canada.

The Canadian Public Health Association described the history of AIDS prevention in Canada as fragmented and confused, facing a hostile political environment, poor coordination mechanisms, and inadequate funding. For the future, they recommended improved consultation for AIDS education; the development of model programs that mobilize key sectors of the community; major projects in health behaviour research; experimental programs for risk reduction among injection drug users; improved communication and resource sharing; and a new integrated approach at the community level, which goes beyond a health promotion approach and requires an integration of disease treatment and prevention strategies (Walters 1989).

The Federal AIDS Strategy has been criticized for not setting targets or guidelines and not taking a comprehensive, coordinated approach to prevention. In addition, the education strategy has been criticized for not moving away from giving basic information to strategies that affect behaviour (Mackie 1990). Although the federal AIDS strategy is considered by some to focus on empowerment and community involvement, the strategy is criticized for its fragmentation and lack of coordination and for following the traditional information dissemination strategy.

Adrien and Carsley (1986) reported that the lack of coordination of prevention and control services is also considered a problem in Quebec. They gave several examples — poor coordination between clinical and diagnostic services, resulting in a waiting period of six weeks for chlamydia

test results; lack of integration of STD education into medical schools; lack of coordination of contact tracing; and a lack of evaluation of educational services. The authors recommended specific objectives for interventions in STDs adapted to the social and administrative context of the various regions of the province. They concluded that the increasing concern shown by both public and health professionals about the sequelae of STDs may help the implementation of a rigorous program of STD control.

Sherris and Fox (1983) reported that the People's Republic of China has one of the most successful national STD control programs. China is the only country that claims to have eradicated syphilis and perhaps gonorrhoea. STDs were controlled through a massive effort, begun in the early 1950s, that included eliminating prostitution, providing STD treatment in all health facilities, educating people about the symptoms of STDs and the need for treatment, and putting political and social pressure on the public and health workers to find all cases and see that they were treated. In the opinion of the authors, STD incidence has remained low since this campaign, mainly because political and social pressures in China discourage sexual relationships outside marriage.

Hume (1987) noted the importance of legislation and regulation in STD prevention efforts in the United States. He observed that all states have laws and regulations regarding the reporting of infectious diseases. Although all require the reporting of syphilis, gonorrhoea, chancroid, lymphogranuloma venereum, granuloma inguinale, and AIDS, there is no great consistency to reporting other STDs. Other laws that he identified as relevant to prevention are those allowing the treatment of minors without notification of parents; the licensing and periodic evaluation of laboratories; and the requirement that laboratories report positive tests to government for epidemiological reasons. He noted that great efforts or advances have not been made in the development of safe and effective immunization for STDs.

The United States has undertaken an extensive public policy initiative in the health promotion field. The Centers for Disease Control have developed national health objectives through a consensus-building process. There are objectives related to STD incidence, specifically to gonorrhoea, syphilis, and chlamydia; sexual behaviour; awareness and education; and the provision of services. Progress in meeting these objectives has been assessed, and it is thought three will be met — those related to decreased incidence of gonorrhoea, syphilis, and gonococcal pelvic inflammatory disease; the remainder either will not be met or cannot be evaluated because of lack of data. The objectives are being rewritten for the year 2000 (Centers for Disease Control 1990).

Shaw (1988) described community organization as a method of mobilizing and involving women in a process of social change that results in the heightened ability of the community to control key aspects of its destiny. She identified this approach as a necessary step to develop the resources, norms, rewards, and sanctions needed within the community to



sustain any individual behaviour change. She stated that new economic resources, housing, drug treatment centres, shelters for battered women, accessible health services, child care, and legal resources are necessary for women in specific communities to be safe in their sexual relationships.

Soskolne and Robson (1989) described a multi-sectoral, multi-strategy approach to AIDS in the Edmonton area. The approach involved an interagency council composed of professionals and lay people who contributed equally to AIDS prevention. The perceived needs of the lay community and the professionals were incorporated and behaviour change theory was applied in all AIDS programming.

## Primary Prevention — Education

Most of the literature regarding primary prevention interventions is based on education strategies. Little literature described interventions that involve other approaches, and even less evaluated outcomes of interventions.

### ***Impact of Education***

Little is known about the impact of education programs on behaviour, often because education is usually part of an overall STD control program; thus, it is not evaluated separately. Also, the desired behaviour changes identified in most education programs — limiting the number of sexual partners, using condoms, and attending STD clinics — are affected by many other factors and are difficult to measure (Sherris and Fox 1983). Very little research has focussed on the best ways to motivate behaviour change, or how to teach the communication and interpersonal skills necessary for adoption of new behaviour.

The few evaluation studies that have focussed on education typically measured gains in knowledge, without assessing changes in behaviour. The study by Alkhateeb et al. (1990) is the most notable example. Other studies have looked at efforts to publicize the availability of STD treatment, which have included various health education messages, but have only assessed their impact on levels of clinic use (Adler 1984; Schuurman and de Haes 1980).

Based on the results of the *Canada Youth and AIDS Study*, King et al. (1988) concluded that educational programs that focus solely on knowledge have clearly been inadequate. However, initial tests of recently proposed sophisticated psychological models for promoting condom use and other safer sexual practices show that change is possible (MacDonald et al. 1990).

These psychological models are aimed at breaking down socialized feelings and thoughts and dispelling fantasies that promote sexual activity but inhibit preventive pregnancy and STD behaviour among teenagers. The models promote the following concepts: acceptance of one's sexuality, setting sexual limits that are in one's best interest, acquiring knowledge about setting sexual limits, negotiating sexual limits with a partner,



consistent observance of agreed-upon limits, and deciding when to move to protected sexual intimacy. The authors conclude that educational efforts should communicate information, foster social support, and provide the means for people to change and maintain behaviour.

Kegeles et al. (1988) studied changes in the perceptions and use of condoms after intensive education with a group of sexually active adolescents between 14 and 19 years of age. Perceptions that condoms were effective in preventing disease transmission were high, but no increase in the use or intention to use condoms occurred. This study took place in a large U.S. city, where media and school coverage of the AIDS epidemic was high. Chervin (1988) and DiClemente (1990) reported similar findings.

Sisk et al. (1988) reviewed educational efforts directed at AIDS and concluded that several public health campaigns for the general population have not produced the desired behaviour change. Others, however, have shown that education through mass media can change health-related beliefs and behaviour, when supplemented with interpersonal communication and skill development to implement new beliefs and motivations.

### ***Experience in Other Countries***

In Sweden, a nation-wide public education program promoting condom use for protection against STDs may have helped to lower the gonorrhoea rate. The National Association for Sex Education began a condom promotion campaign in 1970 as part of a STD control effort involving the government, schools, and private organizations. The campaign used posters, cartoon strips, point-of-purchase displays, and short films. At the same time, the schools began sex education programs. Within two years, the number of condoms sold had increased by 50 percent. The incidence of gonorrhoea had dropped by 20 percent. How much of this drop was due to increased condom use is not known. The increased number of treatment facilities also could have helped to lower the gonorrhoea rate (Wallin 1978).

In Switzerland, the Official Bureau of Public Health commissioned an evaluation of national health campaigns launched in 1987. The result of the study revealed that only 23 percent of men and 10 percent of women used condoms regularly. Out of the 30 percent of youth who had more than four sexual partners, only half used condoms regularly. The authors concluded alternative strategies are needed in prevention, such as travelling exhibitions, mobile "discos," street work, and peer counsellors. They stated that prevention should extend beyond information — youth discussion and participation are essential (Michaud et al. 1988).

Egwu (1985) described a model of sexuality and STD prevention education that recognizes three components. Predisposing factors in sex education are those social and psychological factors that cause individuals or groups to take a particular action. Enabling factors help a person to act or not act on information gained from sex education courses. Reinforcing factors are related to the attitudes and behaviour of health educators and significant others. They are systematically related to communication,

community organization, staff development, supervision, consultation, and feedback — all components of sex education.

One large-scale British government AIDS education campaign aimed at the general public was successful in raising knowledge levels, but failed to change sexual behaviour significantly (Wober 1988). Wober suggested this may be due to a reduced perception of risk in the heterosexual population in Britain as a consequence of the increased knowledge about AIDS.

### ***Education and Religious Organizations***

Religious groups, for the most part, have also embraced education as a response to the AIDS crisis (Melton 1989). Melton reviewed all of the official statements from religious bodies regarding AIDS and reported that among Christian and Jewish groups that have developed a pastoral response to the AIDS crisis, a consensus of opinion has emerged — all groups have demanded increased education and information about the disease with the aim of replacing fear with caution. Religious groups have proposed a variety of programmatic responses that include educating their members through literature. They have also introduced education programs for the secular community, such as schools and businesses.

### ***Special Issues in Education***

Print materials, posters, and handouts are often used to inform the public, but they may be the least effective. However, although these methods alone are inadequate to communicate information leading to behavioural change, full use of the media can fulfil several important functions to help create awareness and political will, to inform decision makers, and to foster community involvement (World Health Organization 1983).

Sisk et al. (1988) have identified one of the problems with AIDS education as the scepticism with which people regard messages from public health experts. The National Center for Health Statistics survey in 1988 indicated that 28 percent of respondents were doubtful about the AIDS information they received from public health officials.

The overall goals of education strategies identified in the literature seem to be to encourage the behaviours that reduce the risk of contracting a STD. Certain behaviours are repeatedly identified in the literature — limiting the number of sexual partners, using condoms and spermicides, and attending clinics for screening.

Two studies combined access to protective devices, such as condoms and spermicides, with education in their model of primary prevention. Solomon and DeJong (1989) made free condoms available to clinic patients through redeemable coupons; patients from both the intervention and control groups took advantage of the opportunity. Stone et al. (1986a) reported the results of a large study in which free condoms were distributed to inner-city, unmarried male adolescents through commercial outlets such

as grocery stores and barbershops. The use of a condom with last coitus steadily increased more than fourfold.

### ***Identifying Risky Behaviours for Education Programs***

To identify needs in education, Lawrance et al. (1990) constructed an AIDS Self-Efficacy Scale to measure the likelihood that preventive behaviours will be adopted. Their study population was 58 pregnant, mostly Black, teen women attending an alternative school in a large city. The scale identified four areas of greatest vulnerability: using condoms, discussing previous homosexual activity, discussing previous bisexual activity, and telling a partner about an experience with a bisexual. The authors concluded that education programs need to give students the opportunity for practising communication skills related to sexual behaviour with their peers, through role-playing and decision-making exercises, to reduce discomfort and prepare them for situations requiring sensitive responses.

### ***Use of Condoms***

If used consistently and correctly, condoms are considered to be highly effective in preventing the acquisition and transmission of most STDs. Efficacy has been inferred from the results of several studies that revealed lower infection rates among correct users compared with non-users and incorrect users. Four experimental studies involving men showed a decreased infection with condom use (Stone et al. 1986b). Condoms may also protect women from STDs. A large U.S. multicentre case-control study (Kelaghan et al. 1982) suggested that women relying on condoms for contraception had a significantly lower risk of hospitalization for pelvic inflammatory disease (PID) than did women who did not. Although the difference was not statistically significant, a case-control study (Austin et al. 1984) showed that female STD clinic attendees whose partners had used condoms in the previous three months were less likely to be infected with gonorrhoea than those whose partners had not. Two prospective cohort studies, Darrow (1975) and Syrjanen et al. (1984), reported that fewer men were infected when condoms were used, but the differences were not statistically significant. Although generally encouraging, these studies, like most observational studies, must be interpreted cautiously. Men who use condoms consistently are likely to differ from those who do not. Most studies have not compared users and non-users with regard to demographic variables, specific sexual practices, frequency of sexual activity, frequency of exposures to infected partners, use of other prophylactic measures, and technical adequacy of condom used.

King et al. (1988) reported condom use of Canadian youth in the *Canada Youth and AIDS Study*. Overall, 74.3 percent of the men and 68.9 percent of the women were sexually active. Of these, 24.8 percent of the men and 15.6 percent of the women reported always using a condom. Fewer students maximized protection by using spermicides with condoms. Just over one-fifth (21.3 percent) of the men and less than one-tenth



(8.6 percent) of the women had 10 or more partners. Of these, 21 percent of the men and 7.5 percent of the women used condoms regularly. Of those who had 10 or more partners, 10.6 percent of the men and 24.2 percent of the women reported having had a STD. Of the women who reported having one or two partners and consistent condom use, 2.5 percent reported a previous STD. Of the women who reported having five or more partners and inconsistent condom use, 25.1 percent reported having a previous STD.

The factors most strongly associated with not using a condom were more sexual partners (for women), embarrassment about the purchase of condoms, difficulty discussing condom use with a partner, use of oral contraceptives, insufficient knowledge of STDs, and the belief that condoms interfere with pleasure. The data also suggested that the fear of pregnancy and the fear of STD motivate condom use. A strong association was found between decreased condom use and increased reliance on oral contraceptives, especially among women with more partners.

Men have been shown to object to condom use more than their female partners, and they frequently cite impairment of pleasure as the reason. However, several large studies have demonstrated an acceptance of condoms by both men and women. In one study, most of the men and women attending a STD clinic claimed that they would not object to either using condoms or having their partners use condoms, and most claimed that they would not be ashamed to ask for and buy condoms (Felman 1979). Stone, Grimes, and Magder's large study involving distribution of free condoms to inner-city, unmarried male adolescents through commercial outlets showed that nearly equal numbers of recipients reported condom use for protection against STDs and to prevent unwanted pregnancy in their partners. Another frequently cited reason for condom use was "because the girls wanted me to" (Stone et al. 1986a).

Tanner and Pollack (1988) hypothesized that erotic experiences with condoms would cause attitudes toward condoms to become more positive. Heterosexual couples (university students) were randomly assigned to three conditions — receiving condoms with instructions on how to incorporate them into sensuous foreplay, condoms only, or no condoms and no instructions. All couples received pre- and post-tests and the analysis revealed that only those who received erotic instructions had significantly enhanced attitudes toward condoms. The instructions focussed on pleasurable sensory experiences with condoms and involved the female partner in the application of the condom. The authors concluded that the introduction of pleasurable sensory motor experience may be more powerful than the higher level cognitive approach characteristic of formal education. This intervention was equally successful with both sexes, in contrast to previous studies. Analysis revealed no differences among groups in erotophilia-erotophobia scores or in the ranges of sexual experiences.



Kirscht (1983) claimed that practices that counteract social norms that inhibit condom use should be discouraged, and replaced with beliefs and norms that favour condom use and safer sexual practices.

### *Use of Spermicides*

Spermicides kill most organisms that cause STDs and are readily available in retail stores. One recent U.S. study found that spermicide users had a gonorrhoea rate one-fourth that of users of oral contraception or voluntary sterilization (Jick et al. 1982).

Vaginal spermicides appear to lower the risk of acquiring gonorrhoea. In the largest randomized clinical trial (Cutler et al. 1977) women recently treated for gonorrhoea, who were assigned to receive nonoxynol-9 foam for six months, had a significantly reduced rate of re-infection that was 10 times lower than that of the control group. The result of a double-blind randomized clinical trial (Rendon et al. 1980) showed a reduction in gonorrhoea (although not statistically significant), and those of a community trial (Cole et al. 1980) showed the risk of re-infection of gonorrhoea was 50 percent lower when a spermicide was used. The results of a cross-sectional study showed the risk of gonorrhoea to be 60 percent lower with the use of spermicides (Quinn and O'Reilly 1985).

Three case-control studies also have demonstrated a protective effect of spermicides on STDs. In one (Jick et al. 1982), women who used spermicides had one-tenth the risk of developing gonorrhoea compared with women using oral or surgical contraception, a highly significant difference. The results of another large study (Kelaghan et al. 1982) showed that those women using spermicides alone had a 30 percent lower risk of hospitalization for first-episode PID, compared with that of women not using contraceptives. In the third study (Austin et al. 1984), women who used spermicides alone had only a 10 percent reduction in the risk of gonorrhoea, compared with that of women not using condoms, diaphragms, or spermicides. However, when spermicides were used with either condoms or diaphragms, the risk of gonorrhoea was reduced by 60 percent. Unlike the other case-control studies, this one controlled for the potentially confounding effects of differences in sexual activity.

Two randomized clinical trials, one community trial, one cross-sectional study, and four case-control studies have all shown a lower risk of STD among users of spermicides. The consistency of these findings by different investigators, with different study populations, and with different study designs suggests that this protective effect is real. In spite of such findings, almost all programs directed at sexual behaviour change are aimed at limiting sexual partners and using condoms.

Although spermicides appear to be highly effective against gonorrhoea, their effect against chlamydia is not documented.

### ***Factors Influencing Behaviour***

A review of educational interventions aimed at changing sexual behaviour is incomplete without an examination of the factors influencing that behaviour. Little in the literature accomplished this, compared to the literature on educational interventions and on the medical approach to control.

Baldwin and Baldwin (1988) surveyed a random sample of 1 426 university students in southern California to determine the ways in which AIDS-related risk-taking behaviour is influenced by various factors. Sixty-six percent ( $n = 851$ ) of the students replied. The dependent variables were measures of actual sexual behaviours that influence risk — the frequency of condom use during vaginal intercourse, the number of sexual partners in the three months immediately preceding completion of the questionnaire, and the degree to which the respondent engaged in casual sex during these three months. The most consistent predictors of cautious sexual behaviours were age at first intercourse, average number of partners per year, being female, and using seat belts while driving. Safer sexual practices were not influenced by religiosity or having had a course on human sexuality or religion. The earlier the age of first intercourse, and the more partners the young person had, the greater the likelihood of engaging in risk-taking behaviours. The more likely the person was to wear a seat belt, the less likely that person was to engage in risk-taking behaviours. Women were less likely to engage in risk-taking behaviours. People who considered themselves more at risk had more sexual partners. Worry about contracting AIDS had a mixed effect on behaviour. Higher parental income and education correlated positively with condom use. The authors concluded that a generalized tendency may exist for some people to take risks while others are less inclined to do so, and people's inclination for risk taking may be an important determinant of their sexual risk-related activities. General habits of caution and sexual conservativeness may be important precursors of safer sexual practices, in which case it might be advisable to increase our emphasis on socializing young people to be more cautious about a variety of risky activities. A broad-based education on the use of pragmatic reasoning for minimizing risks could foster generalized habits of cautiousness that might help to reduce a variety of risky sexual behaviours. AIDS education programs that advocate abstinence or focus primarily on relaying accurate knowledge about AIDS and condom use may have limited impact.

Brown (1983) held the view that contraceptive use is not socially sanctioned or reinforced for teenagers. Messages about contraceptive use received by teenagers are negative; the content usually involves the prevention of unwanted pregnancies and STDs. Negative contraceptive attitudes and inefficient use may result because, during childhood and adolescence, sexual behaviour is not integrated with permissible cognitive knowledge about sex.

Lindemann (1988) conducted a demonstration project that offered counselling by a social worker to any patients who had a STD who accepted the offer. The case notes were qualitatively analyzed for data on the disclosure of having a STD to sexual partners, to determine which factors influenced the disclosure. The analysis revealed six psychosocial factors that may contribute to difficulty in meeting this responsibility: lack of information about STDs; lack of awareness and understanding of the need for disclosure; apprehension about the disclosure; client reaction to the prospect of disclosure; anticipation of the partner's reaction; and the actual reaction of the partner.

Since case finding is presently the major public health method of controlling the spread of STDs, these factors are critically important.

Ross (1984) found that between 15 percent and 28 percent of the variance in the number of sexual partners of homosexual men ( $n = 604$ , four countries surveyed) was accounted for by specific psychosocial factors. Predictors included masculine and feminine personality traits, relationships with mother, degree of homosexuality, perceived societal attitudes toward homosexuality, age, and education. The data strongly suggested that psychological approaches to treatment and prevention of STDs may be warranted.

### *Social Norms*

Results of sociological and anthropological studies suggest that risk perceptions are heavily influenced by political, cultural, and social factors. Attitudes toward risk are often subjective, closely embodied in a system of beliefs, values, and ideals that constitute a culture (Nelkin 1987).

Hacker (1989) identified social norms that influence adolescent sexual behaviour. The sexual norms under which our society operated before World War II were that sex is "bad," except in marriage, but parenthood is "good." This norm incorporated the premises that sex is equivalent to intercourse only, children are asexual, and sexual thoughts, emotions, and fantasies are just as evil as sexual deeds. This norm worked for a long time, because all institutions and authorities reinforced it. After the war, with increasing prosperity, a large middle class enjoying a high level of affluence, and the desire to explore new values and risk new adventures, old sexual norms were rejected. The new sense of freedom and exploration not only affected youth, but gave impetus to the women's movement and the civil rights movement. However, having arisen under the old restrictive rules, the exploration was accompanied by little knowledge and by enormous guilt and shame. Two co-existent moralities resulted: one that has encouraged more sexual freedom; the other that is characterized by embarrassment and shame. As a result, adolescents are reluctant to anticipate upcoming intercourse. The old norm of denial is no longer working but no new one is ready to take its place.

Hacker (1989) recommended working toward a new sexual norm, no longer one of denial, but one of acknowledgment that we are sexual beings.



Within this belief system, sexuality would be “good,” but unwanted parenthood would be “bad.” The belief system includes the premises that people are sexual from birth, and all thoughts, feelings, and fantasies are normal. She recommended that sexuality education include teaching about the hierarchy of risk related to sexual activity, the advantages of postponing intercourse and focussing instead on enhancing one’s sensuality, and about characteristics of our present-day culture related to peer influence and social pressures.

Fisher (1988) highlighted psychological processes by which social influence may affect people’s levels of AIDS knowledge, risk, and prevention behaviours. Such processes include those associated with group norms, social network membership, conformity pressures, social comparison, and modelling, among others. Fisher argued that an important component of similar societal changes, such as behaviours toward minorities and smoking habits, is that these activities have become inconsistent with prevailing norms and values. They recommended strategies to make STD preventive behaviours more consistent with reference group and social network values, and to reframe preventive behaviour so it appears to be consistent with group norms, instead of changing group values themselves.

### *Psychological Influences*

The target behaviour in STD education is closely linked to personal identity. For example, the psychosocial milieu in which adolescent girls first become sexually active is significantly different from that of adolescent boys; accordingly, their perceptions of their sexual behaviour and the implications for sense of self are also different. For everyone, heterosexual or homosexual, sexual behaviour is not merely an act, but a means by which people play out their sense of identity, from which they derive personal meaning and definition. For example, having multiple sexual partners has been for many gay men a political right and a symbol of fraternity. When educators exhort people to change sexual patterns, they call into question issues of personal identity, and can be perceived as asking them to weaken important social bonds. At least in part for this reason, sexual behaviour has, in the language of one health behaviour model, “low changeability” (Solomon and DeJong 1986).

When seeking treatment, many STD patients are in a state of agitation. They are concerned about their health, but with widespread (though sometimes misplaced) confidence in the ability of a pill or shot to cure them, they are often more worried about the social consequences of the diagnosis. One way to mitigate stress is to balance fear-arousing information with constructive suggestions for purposeful action. People are more likely to deny the validity of a message, dismiss its applicability to themselves, or adopt a fatalistic attitude if they are not presented with concrete steps they can take on their own behalf. Although educational materials must include information on what one should not do, the



emphasis should be on what can be done and how to do it in the most personally satisfying way.

Fisher (1990) noted that it is important to realize that adolescent pregnancy and exposure to STDs are problems with similar behavioural causes and similar possibilities for behavioural prevention. On the causal side, present patterns of adolescent sexual behaviour elevate risk of both unintended pregnancy and STDs. On the prevention side, behaviours such as sexual limit-setting, pre-sex discussion of prevention, and consistent contraceptive and condom use could reduce both pregnancy and STDs.

Fisher also described both emotional and structural barriers to STD prevention. Adolescents may be erotophobic (mostly negative in their feelings about sex), erotophilic (mostly positive in their feelings about sex), or anywhere in between these emotional extremes. Moderately erotophobic teenagers are at greater risk of pregnancy and STDs: they may be just comfortable enough about sex to engage in intercourse, but they may be far too uncomfortable to plan for and practise preventive behaviours (Fisher et al. 1988).

Structural barriers influence adolescent behaviour because, to prevent pregnancy and STDs, they must perform complex and difficult sequences of behaviours that are rarely taught explicitly and often disapproved of socially. They include self-acceptance of one's own sexuality; making an advance decision that sexual limits are in one's own best interest; learning how to set sexual limits with a partner; consistently observing agreed-upon limits; and deciding when to move on to greater, but protected, sexual intimacy. These complex responses must be learned, practised, and enacted (Fisher 1990).

The issue of social assertiveness in AIDS preventive behaviour was illustrated by Millan and Ross (1987) who found that, among homosexually active adolescents, 26 percent had engaged in activities that placed them at risk for HIV infection due to lack of assertiveness and having unsafe sexual activities imposed on them. In adults, Ross (1988) reported that an assertive personality style is associated with positive attitudes toward condom use. Ross et al. (1989) developed a scale to evaluate the social and interpersonal skills of adolescents in AIDS-related and non-AIDS-related interactions. The subjects were 101 Australian students. The findings indicated that ratings of AIDS-related activities of the adolescents were not significantly different from their ratings in other social activities, suggesting that levels of comfort and assertiveness among adolescents in AIDS-related activities can be modified.

Salt et al. (1990) described the outcome of whether condoms are used or not as the product of the interaction between the couple and the context of their relationship. They reached the conclusion that when studying populations, grouping people according to their actual behaviour as opposed to risk groups is likely to yield more valid and useful data.

### *Drugs and Alcohol Use*

Stall (1987) examined the data in the AIDS Behavioural Research Project (1984-85,  $n = 463$ ), and determined a strong association between drug and alcohol use during sexual activity and high-risk sexual behaviour in gay men. Since the use of alcohol is so established, the authors concluded that the most effective preventive strategies should focus on avoiding the combination of substance use and sexual activity. Education strategies should be aimed at informing the population of the excess risk associated with combining drug and alcohol use with sexual activity, and should be aimed particularly at those who are most likely to combine the two activities. However, the authors asserted that effective prevention policy should rely on more than education. They gave examples of strategies — making condoms readily available in gay bars, showing bartenders how to identify and “cut off” intoxicated patrons, and finding settings for gay men to meet that are not alcohol-related.

Baldwin et al. (1990) identified that the prevalence of drug- and alcohol-related problems among those who engage in high-risk sexual behaviour would suggest that drug and alcohol use are important target behaviours for health education and behaviour modification. Aral and Holmes (1991) indicated that recent studies in urban areas of the United States have found that transmission of gonorrhoea, syphilis, chancroid, and HIV infection has been associated closely with the exchange of sex for drugs such as crack. Women, particularly adolescents, sometimes engage in multiple sexual contacts to support their addiction. Plant et al. (1989) reported that prostitutes and their clients often make contact with each other when one or both is under the influence of alcohol or other drugs. Heavy drinking and the use of illicit drugs are widely reported to be common among male and female prostitutes.

### **Risk Reduction Education**

The literature has shown that primary prevention strategies are usually educational efforts to try to change risky behaviour. However, no unifying theory is in the literature that was reviewed that could be used to influence behaviour or convince people to modify their lifestyles in ways that would reduce risk.

Three components are identified to be essential for effective STD/HIV risk reduction education.

- The program must provide relevant information about STDs that allows students both to assess their personal risk objectively and to ascertain the best method of risk reduction within their individual social environment.
- The program must provide training in the specific behavioural skills that are necessary for practising safer sex, such as how to introduce the topic of safer sex in pre-intercourse discussion, how to negotiate condom use with a potentially unwilling partner,

and how to exit unsafe sexual situations if a partner refuses to comply with safe sexual requests. Experience with such behaviourally focussed interventions has shown them to be successful in reducing the risk of unintended pregnancy (Fisher 1990; Schinke 1984; Kelly and St. Lawrence 1988b).

- Individuals must be motivated to act on their knowledge of personal STD/HIV risk by using behavioural risk reduction skills.

Baldwin and Baldwin (1988) found that while students in their survey scored high on knowledge of AIDS transmission, and a few reported worrying about the disease and assessing themselves to be at risk, none of the cognitive-emotional variables had much influence on increasing cautious behaviour. Students who had accurate knowledge about AIDS transmission did not engage in markedly safer sexual practices than less knowledgeable students.

Howard (1985) exhorted that knowledge alone does not change behaviour. The growth and development of adolescents affect their ability to use information to control behaviour. Programs designed to help adolescents deal with the social and peer pressures that influence behaviour have shown more success than those that only educate them about the risks of their behaviour. Howard cited S.P. Schinke's work indicating that the use of skill-building techniques regarding communication, combined with knowledge and behavioural practice, increased the ability of school-age youth to prevent unwanted pregnancy (Schinke 1982).

Becker and Joseph (1988) noted that communication and interpersonal skills must be taught as well as technical skills. Knowing how to use a condom is not sufficient to lead to behaviour change if a person cannot ask a partner to use a condom. Techniques such as role playing and behavioural rehearsal may be useful. There is also tangential evidence that helping people learn to deal pragmatically, cautiously, and in a socially responsible manner with various risky activities (such as drinking, driving, drug use, contraception, sexual relations, and STDs) might help to establish generalized habits of cautiousness that would reduce unsafe sexual practices (Bayer 1989).

Fisher (1990) suggested two strategies to reduce negative emotional responses to preventive behaviour: a fantasy walk-through of the sexual limit-setting, contraceptive use, and STD-prevention sequences; then an "*in vivo*" walk-through involving role play. He also recommended that research be conducted in groups targeted for educational intervention to determine the nature and incidence of their anti-prevention beliefs. Once clusters of beliefs common to a group have been identified, they may become the target for values-clarification discussion. Fisher also suggested using videos to replace sexual imagery without a prevention component with positive imagery of sex that includes appropriate preventive behaviours. Zabin et al. (1986) reported that when sex-related prevention interventions are



effectively supported by community resources, the interventions may be relatively successful. Such accessible resources include information about where people can purchase condoms late at night, STD hot-lines, the address and hours of a STD clinic, and similar information.

Van Dam (1989), in his review of AIDS education programs, also concluded that the seemingly more successful approaches are those that involve the target group actively rather than passively. He described this approach as originating in well-defined and well-organized groups that, perceiving themselves to be at risk, feel a need for education. This approach also makes use of existing social networks and infrastructures to reach the members of the community.

Nelkin (1987) stated that educational efforts are only successful in inducing behavioural changes if they are pursued intensively, systematically, and in combination with other intervention strategies. She cited the North Karelia project in Finland, which evaluated a public health model of intervention that combined education measures, community organization techniques, and mobilization of existing social services. The results of the study showed that information from credible sources reinforced by adequate community and counselling services, social support, and an environment that created opportunities for health action, did induce people to change their behaviour.

#### *Risk Reduction — AIDS*

Some analysts have attributed the dramatic changes in sexual norms within the San Francisco homosexual community partly to community-based AIDS risk-reduction programs. The model includes the following:

- strong leadership from within the homosexual community;
- market research to identify appropriate messages and communication channels for reaching the target audience;
- implementation of programs to inform and motivate target audiences;
- focus on facilitating social and cultural change;
- reliance on multiple channels of communication, including print and broadcast media and face-to-face interventions; and
- broad-scale, grass-roots participation in program design and implementation (Sisk et al. 1988).

There is limited evidence to link any aspect of the program to the behavioural change observed. Given the unique composition of the San Francisco homosexual community, the prevention model used there might not succeed in areas where homosexuals are not open about their sexual orientation and do not identify with the homosexual community.



*Risk Reduction — Clinic Settings*

Most STD prevention efforts have occurred in clinics. The reasons cited are that clinic-based education enables providers to reach people who, if uninformed or otherwise unmotivated to implement treatment and prevention behaviour, could easily transmit the disease to others; most patients seen in STD public health clinics have been previously infected with a STD at least once; many of these re-infections could have been avoided with appropriate education; the point of diagnosis constitutes a teachable moment; and, according to the health belief model (Becker 1974), patients with positive diagnoses are more likely to recognize their susceptibility and to respond to education messages that will help them avoid recurrence.

Stone et al. (1986a) observed that primary prevention of STDs has received little emphasis in control programs. To evaluate the effectiveness of prevention strategies, the authors reviewed the international literature on this topic. They concluded that the use of condoms and spermicides greatly reduces the risk of gonorrhoea, and barrier methods are practical and acceptable. They found that certain systemic antibiotics are effective but, for practical reasons, their use cannot be recommended. Although the effectiveness of modifying sexual behaviour to reduce the risk of STDs has not been evaluated, Stone, Grimes, and Magder stated that many people have changed or are willing to change their behaviour. Even if preventive measures are used consistently by only a minority of persons at risk, rates of STDs would decline rapidly. The authors calculated that reducing the probability of transmission of gonorrhoea by 10 percent per partner would reduce the prevalence of gonorrhoea in the heterosexual population by more than 50 percent.

Sisk et al. (1988), in their review of educational strategies, reported that studies in STD clinics suggest that special education interventions can improve knowledge and affect attitudes toward preventive behaviours. They concluded that person-to-person interviews are most effective.

Solomon and DeJong (1986, 1989) conducted a study in a STD clinic in a large city hospital, where they randomly assigned clinic attendees to an intervention group that watched an educational videotape. The tape portrayed the use of condoms as socially acceptable and normative behaviour, and focussed on the development of interpersonal and communicative skills. Subjects who saw the videotape scored higher on knowledge assessment and had more accepting attitudes toward condoms than the treatment group. A second study was conducted in which both groups were given coupons to redeem condoms. Intervention group subjects were more likely than control group subjects to redeem coupons, but both groups exhibited a high level of interest in the free condoms. The finding that both groups in this study sought free condoms strongly suggests that if STD clinics offer free condoms, they will be accepted by most patients. The authors indicated that a major limitation of this study is the difficulty in measuring changes in actual condom use.

### *Risk Reduction — School Programs*

Sacks et al. (1983) conducted a survey of directors of provincial venereal disease control programs to determine the extent of STD education in schools. In five provinces, information at the secondary school level was being disseminated and in at least one province, no STD education was taking place whatsoever. Schools were only intermittently covered, and not all of the students were involved in the program. In addition, the level of content of information was considered to be variable, and the use of outside STD educators was seldom welcomed in the schools. The teaching was generally considered to be inadequate. The respondents suggested that STD education should be incorporated into the school curriculum with the assistance of outside personnel knowledgeable in the field of STD education.

Sisk et al. (1988), in their review of education strategies, reported that results from numerous evaluations indicate that sexuality education programs in schools increase factual knowledge about sexuality and STDs, but have little measurable impact on attitude or behaviour. The authors cited two exceptions. One program, directed at preventing unwanted pregnancy, taught communication and problem-solving skills through role playing and rehearsal (Schinke et al. 1981). The other was a community-based program in rural South Carolina that used parents, churches, schools, other community organizations, and the media, which seemed to have lowered teen pregnancy rates (Vincent et al. 1987).

The findings of an evaluation of a school program aimed at reducing smoking and drug use are relevant to STD education. Ary et al. (1990) evaluated the effects of a social influence intervention in a school-based smoking and drug use prevention program. Their study was a randomized trial in 37 schools, where the school was the unit of randomization and the unit of analysis. (This avoided overstating the effects of the intervention when the interdependence of subjects in the same school may be responsible.) The intervention addressed social influence factors and skills training. After one year, there was a significant treatment effect on smoking; however, it had no effect on alcohol or drug use. The authors concluded that problematic levels of substance use among young people need to be considered as one facet of a more general syndrome of problem behaviour. A more comprehensive effort is needed to examine the value of efforts aimed at modifying the social context that produces deviance-prone youth. Current organizations tend to focus on research into the prevention of each problem behaviour separately, and discourage funding for the evaluation of comprehensive programs.

Howard (1985) conducted a field test on an educational program designed to help adolescents resist the social and peer pressures that can lead to early sexual involvement and thus help curtail STDs and premature pregnancy. The program helped adolescents to recognize social pressures and peer pressures, provided information about levels of expressing affection physically, and provided opportunities to hear older adolescents

role-model attitudes and skills directed toward resisting pressures to become sexually involved. In addition, it provided exercises to practise such skills. After the program, the participants reported that they were more aware of the pressures to become sexually involved and that they had learned skills to help them to say no. Six months to two years after participation in the program, only 10 percent of those 16 years of age or less who had participated had had sex, in contrast to the national level of 28 percent.

Baldwin et al. (1990) tested the effectiveness of a 10-week university course on human sexuality in changing fertility-related and AIDS-related behaviour of students. The experimental group consisted of 267 students randomly selected from all students enrolled in a human sexuality course; the control group was randomly selected from students who did not take the course. A pre- and post-test design revealed that the experimental group showed significant increases in knowledge about the likelihood of contracting the virus responsible for AIDS from one act of intercourse, and reported increased worry about contracting AIDS. Compared with the control group, the experimental group increased certain cautious behaviours, such as being more selective in their choice of sexual partners and asking their partners more questions about their AIDS-related behaviour. However, the course did not lead students to increase the use of condoms significantly, decrease the number of sexual partners, or spend a longer time getting to know new partners before engaging in sexual activity.

A study by Croteau et al. (1981) showed that students in Quebec secondary schools who had a positive attitude about sex (as assessed by the authors' testing methods) had a lower incidence of sexual activity. The group of students studied had a mean age of 15.5. Sexual activity was unrelated to socioeconomic status but was related to age and lifestyle. However, the positive or negative effects of STD education were not assessed in this study. The authors suggested that decision-making ability should be a part of the students' general education.

Community resistance is often cited as a reason not to implement school-based programs. Kroger and Wiesner (1981) reported that the single greatest obstacle to implementing programs dealing with sensitive matters is the fear of community or parental backlash. However, various surveys have shown that children want more STD public education and that most parents favour this education.

#### *Computer Network Health Promotion*

Computers have become instrumental in STD prevention education. Robinson (1989) described a randomized, controlled prospective study that tested the efficacy of Stanford Health-Net in changing community health behaviours. The treatment group, 351 graduate and undergraduate university students, received access to Health-Net, a health promotion computer network emphasizing specific self-care and preventive strategies.



The treatment group displayed a 577 percent greater increase in perceived confidence for preventing the acquisition of a STD than the control group.

Van Cura et al. (1975) used an interactive computer program to teach clinic users about venereal disease and to gain personal information; it was quite acceptable to users. A post-test indicated that the people using the program knew significantly more than the control group.

Deardorff (1986) randomly assigned college students to one of four groups to test different educational methods — computerized, face to face, written, or control. The experimental groups reviewed a lengthy text on STDs; the control group received none. Participants in the computer and written information groups freely recalled information at an equivalent rate that was superior to the face-to-face format.

## Secondary Prevention

### *Detection*

Cates and Toomey (1990) indicated that early detection is crucial to STD intervention and prevention. Case-finding methods include clinical diagnosis based on symptoms and signs, confirmation diagnostic testing in patients with symptoms or signs suggestive of a STD, targeted screening in individuals at risk, broader screening without likelihood of a STD, and examination of sex partners of those with a STD. Diagnostic tests need to be tailored to the specific medical history, sexual history, symptoms, and physical signs of each patient. Because of this targeted approach, primary care clinicians should routinely inquire about the sexual behaviour of their patients and that of their sexual partners.

According to the U.S. 1982 National Survey of Family Growth, of more than 3 000 women interviewed who had made at least one family-planning visit in the 12 months preceding the interview, only 50 percent reported that they were tested for a sexually transmitted infection. Black women were far more likely to have been screened than white women (67 percent compared with 47 percent); this racial differential is seen in every subgroup examined. A large difference was also seen in the proportion screened according to the woman's source of family-planning care: those who attended a clinic were much more likely to have been screened for STDs than women who saw a private doctor (62 percent and 43 percent, respectively). In addition, women who lived in the South were more likely to have been screened than were residents of other regions (58 percent compared with 46 percent). Differences by metropolitan and non-metropolitan area of residence were small and not statistically significant. The authors concluded that since many characteristics believed to be important risk markers for sexually transmitted infections are also predictors of whether a woman will be screened for such infections, current screening practices appear, in general, to target the appropriate groups (Aral et al. 1986).



Similar data are not reported in the Canadian literature.

Schuurman and de Haes (1980) ran advertisements in the sex club columns of two daily papers to direct concerned readers to a pre-recorded telephone message with information regarding STDs. Many calls were recorded, with a 20 percent increase in the number of new patients attending the STD clinic. A 32 percent increase in the number of cultures for gonorrhoea performed at the laboratory was also recorded.

As mentioned previously, Hughes et al. (1989) found a 14.7 percent rate of chlamydia infection in a population of sexually active adolescent girls attending a gynaecology clinic at a children's hospital. The most common reason for attending the clinic was for birth control. Of the 541 girls, 78 percent were asymptomatic. The authors concluded that because of the high morbidity rate associated with genital chlamydia infection and the high prevalence rate among adolescent girls who attended the clinic, most of whom were asymptomatic, all sexually active teenagers should be screened.

Aral and Holmes (1991) recommended screening for chlamydia as part of routine pelvic examination. They stated that chlamydia infection seems to be prevalent among the middle class in the United States because programs recommended for controlling the spread of chlamydia have not been widely implemented. They noted that control programs have effectively reduced the incidence of gonorrhoea and syphilis in middle-class populations.

The Centers for Disease Control have recommended a plan for the control of chlamydia infections in national policy guidelines. They recommended that due to the limited resources available to pay for specific diagnostic tests, resources should be reserved for screening high-risk patients who would not otherwise receive empirical therapy. Clearly, young sexually active women, particularly those using public clinics for STDs or family planning, are recommended for highest screening priority ("*Chlamydia trachomatis* Infections," 1985). Critics believe more widespread laboratory testing is integral to the control of chlamydia infections (Stamm and Holmes 1986).

### **Treatment**

Effective and timely treatment of STDs is identified in the literature as inherent to prevention and control. Selective prophylactic (preventive or epidemiological) treatment has a major role in STD control strategies. In certain instances, waiting to confirm the diagnosis before initiating therapy is considered inappropriate; instead, antibiotics can be administered to people at high risk when confirmation is considered likely. The same philosophy underlies the recommendation for giving tetracyclines concurrently with penicillin to patients with confirmed gonorrhoea infection, because a relatively high proportion is likely to have co-existent chlamydia (Cates and Toomey 1990).

### **Clinical Care**

The potential impact of education for professionals involved in STD prevention is mentioned by numerous authors (Cates and Toomey 1990; Sherris and Fox 1983; Stone et al. 1986a; Cates 1984; Darrow 1981; "Chlamydia trachomatis Infections," 1985). The focus of this concern is on clinical training and medical and academic standing; little attention is paid to values of professionals and their interpersonal skills, including interviewing and counselling. Cates and Toomey (1990) reported that only one in five U.S. medical schools provide STD clinical training for even half of their students.

The 11 Centers for Disease Control in the United States have developed clinical guidelines to assist STD facilities in improving disease management. Regional STD prevention and training centres integrate a university medical school with a model public STD clinic to provide training for mid-career clinicians and students.

One of the centres evaluated the program offered to its students. Course evaluations by students indicated a high level of immediate satisfaction; all courses rated above average to excellent. More negative criticism came from physicians than from medical or nursing students. Learner evaluation showed major increases in short-term cognitive skills, mostly related to patient management. The evaluation of patient care came from the clinicians to whom the students were assigned for their clinical experience, and also from surveys sent out in the mail. The clinical evaluations were inconsistent and varied according to the expectations of each clinician, time spent with each student, and uncertainties about whether they were assessing post-, mid- or pre-course capabilities (Judson and Boyd 1982).

Physicians who are interested in STDs will have to complement their traditional diagnostic and therapeutic skills with additional training in biosocial sciences. Most clinicians do not know how to take an adequate sexual history, and inquiring about the intimate details of their patients' sexual partners does not come naturally. The results of a study of Canadian medical schools (Stamm et al. 1982), with 10 of the 15 surveyed responding, revealed that medical school training was inadequate — both clinically and theoretically.

The results of a study by Canadian researchers in STDs also revealed that research support is not sufficient. In 1981-82, approximately \$650 000 was awarded to individuals and institutions conducting research into STDs; this is less than 0.3 percent of the total Canadian fiscal commitment to medical research and less than 0.4 percent of the estimated medical and hospital costs of STDs. The authors have estimated the costs of STDs in Canada to be from \$150 million to \$250 million. The research was primarily oriented to specific microbiological investigation. There was \$115 000 spent for research into chlamydia and ureaplasma, \$72 000 for herpes, \$55 000 for *Haemophilus ducreyi*, and \$48 000 for gonorrhoea. The research money spent on PID was \$31 000. No significant field studies

investigating the control of STDs or behavioural aspects of these diseases were funded in 1980-81 (Ronald et al. 1983).

Few authors have explored the provision of clinical care within the relevant social or environmental context. Aral and Holmes (1991) suggested that control of STDs in the inner-city "underclass" calls for new approaches, such as satellite clinics in inner-city neighbourhoods, that reach out to the affected communities. Mobile clinics or vans could provide services to the growing homeless population. The inner-city communities and the health sector must work as partners in developing and administering clinical services and behavioural intervention programs. Because diverse health problems often overlap many social and economic problems, public health policies should be coordinated with other programs active in the community, such as job creation, early childhood intervention, low-cost housing, and drug treatment.

### **Patient Counselling**

The literature showed overall consensus that patient counselling is central to quality clinical care and has the potential to contribute to prevention. One of the goals of such counselling is to facilitate changes in behaviour, including responding to suspected disease by promptly seeking appropriate medical evaluation; taking oral medication as directed; returning for follow-up tests when applicable; ensuring examination of sexual partners; avoiding sexual exposure while infectious; and preventing exposure by using barrier protection in high-risk settings.

In addition, goals include helping patients to understand the importance of knowing the risk behaviour of their partners, which sexual practices reduce the potential risk of infection, and the social skills essential to negotiate safer sexual behaviour with future partners (Cates and Toomey 1990; "*Chlamydia trachomatis* Infections," 1985). Fisher (1990) stated that health care providers still seem much more committed to pregnancy prevention in adolescents than to prevention of both pregnancy and STD. For example, each time a sexually active young woman is prescribed oral contraceptives, but is not counselled about condoms, she is put at risk because she is sexually active, unconcerned about pregnancy, and undefended from STD.

O'Reilly and Aral (1985) described approaches that have worked in adolescent-oriented contraceptive clinics that could work in STD clinics. For example, adolescents prefer same-sex examiners and unchaperoned examinations. Adolescent girls fear pelvic examinations because they have been told by others that they are painful; therefore, how the examination is approached is important. The authors stressed that adolescents need confidentiality when seeking medical care.

### **Partner Notification**

Traditionally, partner notification has emphasized active intervention by health care providers to interview the patient, locate the partners, and ensure that partners are evaluated and treated. An alternative approach



to partner notification encourages patients to assume responsibility for locating and referring their own sexual partners. Such an approach actively involves patients in the disease control effort, is relatively inexpensive, is acceptable to many patients, and saves staff time for targeted provider referral. Active referral by health care personnel is more labour-intensive, time-consuming, and expensive; thus, provider referral should be restricted to high-yield cases or to high-risk core environments (Cates and Toomey 1990).

Jamison and Mueller (1979) studied the effectiveness of reducing the rates of re-infection by encouraging gonorrhoea patients in public treatment facilities to become more involved in disease prevention and control. They compared two approaches to interviewing patients — the epidemiological case-finding technique, the traditional approach of the professionals requesting names of and tracing sexual contacts, versus the motivational-responsibility technique, which involves the patient in contact follow-up. Results indicated that re-infection rates were lower for male patients, but not for female patients, who received the motivational-responsibility interview.

Primary care physicians may play a role in avoiding disclosure, particularly when a wife sees a physician for regular gynaecological checkups. Lindemann (1988) has noted that when data from case notes indicate that the husband has previously contracted a STD, the physician may treat the spouse for an infection without disclosing the problem to her. The issue of infidelity seems to generate anxiety in physicians, and the potential need for marital counselling often requires skills and time that they do not have. To avoid this uncomfortable situation, more than half of primary care clinicians surveyed said they would lie to a patient's spouse about the implications of a STD if requested (Novack et al. 1989).

## AIDS and STDs

Most of the literature from 1987 onward — 63 percent, or 78 articles out of 123 reviewed for this paper — specifically addressed AIDS or HIV prevention, and dealt mostly with education. Although it is admitted in the literature that education alone will not work, and that knowledge does not change behaviour, little is found in the experimental literature that tests other models of prevention. Furthermore, the influence of AIDS education programs on other STDs has not been adequately studied.

Some authors noted the large amount of money being spent on AIDS education and control, compared to other STDs. By focussing on AIDS and HIV, other problems are being neglected. Gonorrhoea is the most virulent infection among the STDs. Only about one-third of the actual cases are estimated to be reported; one-quarter of the cases are reported for adolescents. The ratio of chlamydia and gonorrhoea is reported to be from



2:1 to 5:1. No conclusive evidence specifically targeted to AIDS programs has had any influence on the other STDs.

On the other hand, AIDS education has contributed knowledge about the usefulness of a social marketing approach applied to STDs, based on commercial advertising strategies. An advantage of non-clinic-based campaigns is that if the target group is highly organized, educational materials and programs can be delivered to established social networks, whose members are in important relationships, and key opinion leaders can be used as intermediaries. Rothenberg (1983) has demonstrated that some established geographical pockets have an exceptionally high incidence of STDs, and that transmission within those areas can be traced to the particular social groups that congregate in certain localities, such as bars. He recommended targeting STD prevention efforts to well-defined neighbourhoods and carefully planning entry into those social groups for whom the messages are most important. Many local gay organizations have developed successful risk reduction campaigns that take advantage of existing social networks and have the endorsement of opinion leaders within the local community. A good example is house parties, in which one person invites friends over to hear a presentation about safe sex.

## Summary

This overview of current thinking related to the prevention of STDs is based on material prepared for publication in professional and academic journals. As such, it includes the most rigorously evaluated programs, and the opinions and perceptions of many of the leading researchers in the field. However, this paper has not included a critical evaluation of these studies, and the material reviewed does not capture the full range of community-level and policy-oriented approaches to STD prevention. It is unknown to what extent the knowledge presented in this review is reflected in preventive practice in the field.

Nevertheless, material showed that a substantial amount of program development is under way in the field of STD prevention, that social factors are increasingly being considered in the design of prevention strategies, and that multi-faceted approaches that combine disease control and primary prevention are now more common and accepted in the field. Much more work must be undertaken in the areas of research and program development to build on these trends and to address adequately the spread of STDs in Canada.

The literature review of social factors relating to the transmission of STDs and the implications for prevention has revealed that most activity in the health care system relating to STD prevention has been based on the epidemiological or biomedical model. When examining contributing causes, some study has taken place on the behavioural aspects of transmission,

but only so far as direct, observable “face value” behaviours are concerned, for example, whether men wear condoms and whether men and women have casual sexual encounters with several partners. Little in the literature went beyond that examination to determine what motivates those behaviours. One exception is the work of Birch and Stoddart (1990), which looks at the difference between the individual’s perceived best interests and those of society.

Education has been seen as the key strategy in prevention of STDs — particularly HIV. The literature contained many opinions about the benefits of education and what form it should take. The review also revealed that some evaluation of educational interventions is taking place in clinic settings; however, most do not rely on experimental designs.

HIV, AIDS, and related prevention programs have received most of the attention in the literature in the last four years. Although some of these strategies are thought to be effective in addressing the transmission of other STDs, little in the literature supported this supposition. In addition, much of the survey data in the literature examined attitudes and behaviours, but there was little evaluation research.

Since many factors influence knowledge, attitudes, and behaviours, measuring the effectiveness of a specific program requires separating the effects of the program from the effects of other contributing factors. Research methods call for comparing changes in a group that received an intervention with changes in a control group. Different strategies may also be evaluated by comparing changes among groups that have received different interventions. As well, ethnographic research (observation of a group’s beliefs and practices by trained observers) would be useful to design and target interventions. Such research has yielded invaluable insight into drug use and patterns of social and sexual relationships that suggest new educational approaches (Sisk et al. 1988).

Little in the literature described prevention interventions that combine education, mental health services, family planning services, social services, and maternal and child health services. Instead, much of the literature focussed solely on clinical settings or on educational settings.

The literature reviewed did not address thoroughly the factors relating to social norms and group influences and how they affect the transmission of STDs. Virtually nothing in the area of tested interventions was found that might influence group norms.

Overall, according to this literature, a substantial amount of further research and analysis is required to move beyond the epidemiological model of STD transmission and prevention, and to explore more thoroughly the underlying contributing social factors that influence the success of health interventions. This understanding is necessary before innovative and relevant prevention programs can be designed.

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# **Feasibility of Economic Evaluations of Sexually Transmitted Disease Prevention Programs in Canada**

Ron Goeree



## **Executive Summary**

The relative ease with which sexually transmitted diseases (STDs) are spread, the difficulty associated with early detection, and the development of secondary diseases and conditions by a high proportion of those affected have resulted in a shift of attention from treatment to prevention. All too often, however, prevention programs are introduced without accompanying evidence demonstrating their clinical effectiveness and economic efficiency.

The study explores issues of suitability, methodology, and feasibility in relation to economic evaluations of STD prevention programs. Three categories of economic evaluation are discussed: Cost-Benefit Analysis (CBA), which quantifies the value of resources consumed and the value of resources saved; Cost-Effectiveness Analysis (CEA), which measures the value of resources consumed and the clinical effects produced; and Cost-Utility Analysis (CUA), which determines the value of resources consumed and the changes in quality of life. Specific methodological issues to be considered before any economic evaluation of STD prevention can take place are identified. These include such basic questions as what program is to be evaluated; whether the study



can be designed to control for other factors external to the chosen program; how the etiological relationships between STDs, pelvic inflammatory disease (PID), infertility, and other diseases and conditions can be unravelled; where standardized information about STD prevention programs can be obtained; and how information about direct and indirect costs and benefits can be collected.

The study concludes that in the absence of standardized data for economic evaluation, the only alternatives are qualitative assessments of the validity of existing programs.

## Introduction

Sexually transmitted diseases (STDs) are among the most common health problems in Canada. More than 20 varieties of STDs have been identified. Undetected and untreated acute phases of each disease can lead to other chronic diseases and disabilities such as pelvic inflammatory disease (PID), ectopic pregnancy, infertility, and maternal and infant infections during and immediately after pregnancy. For example, *Chlamydia trachomatis*, the most common STD, can lead to upper genital tract infections, such as PID and tubal occlusions, that may result in ectopic pregnancies and infertility. As a result, STDs are a direct source of considerable personal pain and discomfort and can have far-reaching emotional, biological, and economic consequences for those affected, their families and friends, and society in general.

Although STDs are common and widespread, information on the exact incidence and prevalence of each disease in Canada is limited, with the exception perhaps of acquired immunodeficiency syndrome (AIDS). Confidentiality, the desire for privacy, consistent under-reporting, the ambulatory nature of most treatment, and multiple disease incidence all contribute to the lack of reliable information. In addition, not all STDs are "reportable" to provincial departments and ministries of health, and those that are have changed over time. In Ontario, for example, only 8 of the more than 20 varieties of STDs are "reportable" under the Health Protection and Promotion Act. Although national data for these STDs are available, Health and Welfare Canada (1991) reported that these cases account for only a proportion of the total number of cases. The collection of national data on unreportable STDs is virtually impossible. Even more problematic is the multi-factorial sequelae of untreated acute phases of STDs. At best, information on the sequelae of STDs in Canada is available only from isolated studies. For example, Estany et al. (1989) estimated that 50 percent of PID cases are caused by *C. trachomatis* and that approximately 20 percent of these cases would likely develop long-term consequences such as

tubal occlusion. Todd et al. (1988) reported that 17 percent of women become infertile after one episode of PID and 60 percent after three episodes.

The relative ease with which STDs are spread, the difficulty associated with early detection, and the high proportion of infectants developing secondary diseases and conditions have resulted in a shift of attention away from treatment to prevention. Although a shift to prevention is a natural consequence of scientific and technical progress in medicine, all too often these programs are introduced without evidence demonstrating their clinical effectiveness and economic efficiency. Given the shift in attention to prevention of STDs, it is imperative that rigorous evaluations of these programs be conducted. This paper addresses the issues of which economic evaluation technique is best suited for these evaluations, some of the anticipated methodological problems in conducting these evaluations, and whether such evaluations are feasible.

## Types of STD Prevention Programs

Theobald Smith conceptualized the determinants of infection and the means of preventing it as follows:

$$\text{Infection} = \frac{\text{Inoculum} \times \text{Virulence}}{\text{Host Defence}}$$

According to this simple conceptualization, prevention is a function of

1. reduction in, or elimination of exposure to, infectious agents (inoculum);
2. impedance of virulence factors;
3. increased host defences; and
4. combinations of any or all of the above.

The relationship between infection and its determinants is particularly useful in distinguishing between the three main types of STD prevention programs: primary, secondary, and tertiary.

Primary prevention programs are aimed at reducing or eliminating the exposure to infectious agents. They are intended to prevent the disease or disorder from occurring. Examples of primary prevention programs include barrier contraceptives and education programs (e.g., school-based, target group-based or general public-based safe sex promotion and STD awareness programs). Education programs are communicated through a variety of methods, including print material, videos, and teaching/instruction seminars.

Secondary prevention programs are intended to interrupt or minimize the progression of the disease. The intention of these programs is to intervene before irreversible damage has occurred. Examples of secondary

prevention programs include disease reporting; contact-tracing programs; partner notification programs; screening and diagnostic programs; and increased accessibility programs (e.g., localized clinics and hot-lines).

Tertiary prevention programs are designed to alleviate already irreversible diseases, slow their progression, and prevent further consequences of the disease or disorder. Although labelled as preventive programs, such programs are actually treatment-oriented (e.g., drug therapies, palliative care, treatment of negative sequelae of STDs). Unlike the intermediate "process" characteristic of primary and secondary prevention programs, the care required in tertiary programs is an outcome of interest. This distinction between prevention and treatment (i.e., process versus outcome) will be particularly important when defining the parameters of the evaluation.

## Defining the Parameters of the Evaluation

Although obvious, a crucial and necessary starting point in any evaluation is defining exactly what is to be evaluated. Since an economic evaluation must involve a comparison of two or more alternatives, and given the three types of prevention programs mentioned previously, several different evaluations could be conducted:

- (a) one primary prevention program against another primary prevention program;
- (b) one or more primary prevention programs against no primary prevention program;
- (c) one or more primary prevention programs against one or more secondary prevention programs;
- (d) one secondary prevention program against another secondary prevention program;
- (e) one or more secondary prevention programs against no secondary and no primary prevention program; and
- (f) a "package" of primary and secondary prevention programs against another "package" of primary and secondary prevention programs, or against no primary or secondary prevention program.

This list is intended to be illustrative of some comparison permutations and is not an exhaustive list. The list helps, however, to emphasize the complexity of evaluating a prevention program in this field. Issues of contamination and co-intervention (discussed in a later section) are obvious and seem inevitable. Nevertheless, it is important to decide, at the outset, which programs or package of programs are to be evaluated.

Absent from the list of potential evaluations is any mention of comparisons against tertiary prevention programs; this is because all of the comparisons mentioned necessarily include tertiary prevention programs. For example, one of the benefits of a primary or secondary prevention program is the number of tertiary level cases averted and therefore treatment costs averted. We assume that, once an infectant reaches the tertiary level, all will be done to alleviate already irreversible diseases, slow their progression, and prevent further consequences of the disease. The outcome, treatment-oriented nature of tertiary prevention programs determines that they will always be included in the evaluation, no matter which parameters are chosen.

## Types of Economic Evaluations

Deciding what is to be evaluated is important for also deciding which type of economic evaluation to use. The fundamental components of a formal economic evaluation are as follows:

<b>INPUTS</b>	→	<b>HEALTH CARE SERVICES</b>	→	<b>OUTPUTS</b>
(Resources consumed)				(Improvements in morbidity, mortality, health status)

More specifically, Green and Gordon (1982) described the input-output relationship for prevention programs as follows:

<b>PROCESS</b>		<b>IMPACT EVALUATION</b>		<b>OUTCOME EVALUATION</b>
<b>Objects of interest in evaluation:</b>				
Health education program	→	Predisposing, enabling, and reinforcing factors	→	Protective behaviour
			→	Health
				Social benefit
<b>Standards of acceptability in evaluation:</b>				
Peer review, quality control, accreditation, audit, certification	→	Changes in knowledge, attitudes, beliefs, skills, resources, social support	→	Changes in frequency, distribution, timing, or quality of behaviour
			→	Changes in mortality, morbidity, or disability
				Changes in quality of life



The important feature of this input-output relationship is that effectiveness cannot be assessed without reference to both inputs and outputs. Because several alternative approaches can be taken to quantify outputs or outcomes of an intervention, three main types of economic evaluations have emerged. Broadly categorized, these types of evaluations and the approach used to measure their inputs and outputs are as follows:

Type of Evaluation	Inputs	Outputs
Cost-benefit analysis (CBA)	\$ value of resources consumed or saved	\$ value of benefits of program
Cost-effectiveness analysis (CEA)	\$ value of resources consumed or saved	Clinical effects produced
Cost-utility analysis (CUA)	\$ value of resources consumed or saved	Changes in quality of life

Determining which type of evaluation is best suited for an analysis depends largely on the objective of the evaluation and the nature of the outputs. A CBA has the advantage that all inputs and outputs are measured in similar units (i.e., dollars). If benefits achieved are greater than costs incurred in achieving those benefits, then the program is worthwhile. The disadvantage of a CBA is that many programs (including STD prevention programs) have benefits that are very difficult to value in monetary terms. For example, what is the value of decreased pain and suffering as a result of preventing a disease? What is the value of being reassured of not getting a disease? What is the value of avoiding ectopic pregnancies, infertility, or sterility? These benefits of STD prevention programs are difficult (and some would argue impossible) to quantify in monetary terms.

As suggested by Drummond et al. (1987, 74) a CEA may be appropriate if "there is one, unambiguous, objective of the intervention(s) and therefore a clear dimension along which effectiveness can be assessed." In the case of STD prevention, the objective is clearly the prevention of sexually transmitted diseases. Leaving the output of the intervention in natural units (i.e., cases prevented) avoids the contentious issue of placing monetary values on intangible items such as pain and suffering, reassurance, and infertility. The main disadvantage of a CEA is that effectiveness measures are intermediate outputs and they vary across evaluations. The policy maker must decide, for example, whether a particular cost per STD prevented is better or worse than a cost per unit of effect from other programs (e.g., cost per life saved or life-year gained). Because the effectiveness measures are different, this decision necessarily involves making a value judgment.

A CUA may be appropriate if quality of life is the important or an important outcome of the intervention. In a CUA the effectiveness measures are expressed as final outputs (i.e., quality of life improvement) and, therefore, results from CUAs can be directly compared across evaluations. A cost per unit increase in quality of life from a STD prevention program can be directly compared to the cost per unit increase in quality of life from other health care interventions. The disadvantage of a CUA is that measurements of quality of life must come directly from STD infectants and potential infectants. Obtaining reliable measurements for this type of evaluation is expensive and time-consuming, and they must be updated regularly.

## Structuring an Economic Evaluation

The categories of costs and benefits used in economic evaluations are similar regardless of the type of evaluation. For evaluations of STD prevention programs, the categories are as follows:

### **Direct costs**

- Cost of setting up and operating prevention program
- Patient out-of-pocket costs for participation in program

### **Indirect costs**

- Productivity losses as a result of participation in program

### **Direct benefits**

- Treatment and other health care costs averted
- Patient out-of-pocket costs averted

### **Indirect benefits**

- Productivity gains as a result of averted illness/disability
- Intangibles (e.g., value of pain, suffering, infertility averted)

As mentioned previously, what differs between the types of economic evaluations is how the effectiveness outcomes are valued or measured. A CBA of a primary prevention program compared to no program places monetary values on the program outcomes. A CEA would leave the outcomes in natural units, resulting in a net cost (gross costs minus benefits) per STD averted. For a CUA, the resulting ratio would be a net cost per unit change in quality of life (see "Types of Economic Evaluations" above).

## Cost Evaluations and Their Limitations

A cost evaluation is one that focusses specifically on the cost of a program, disease, or disability. Such evaluations are not full economic evaluations because they do not involve a formal comparison of two or more

alternative interventions. They do not consider the extra or incremental cost of one program over another, compared to the extra or incremental outputs it generates (e.g., incremental cost per STD averted). This limited scope is criticized because a full comparison of one program over another is needed to address the question of whether a program is necessary or whether one program is better or worse than another. For prevention programs, even the "no program" or "do nothing program" is an alternative that needs to be incorporated into a formal evaluation.

An example of a cost evaluation is a cost of illness study. Todd et al. (1988) estimated the direct and indirect cost of PID and associated sequelae in Canada in 1985 to be over \$140 million. Health and Welfare Canada (1990) estimated the personal direct cost for each person with AIDS in Canada in 1988 to be \$82 500 per year. Washington et al. (1987) estimated that *C. trachomatis* infections cost Americans over \$1.4 billion per year. Although incomplete, such evaluations help to highlight the significant cost implications of STDs, especially the cost of associated sequelae.

## Methodological Considerations for an Economic Evaluation

Many of the methodological issues that surface during an evaluation are difficult to predict at the conceptual level. Most of these issues arise because of the type of information that is available and how it is reported. These issues are not discussed.

Some general methodological issues, however, are common to both types of prevention programs and need to be addressed before an economic evaluation of a STD prevention program can be conducted. Some of these issues are discussed below.

### What Is to Be Evaluated?

As previously mentioned, an essential starting point is deciding exactly what it is that needs to be evaluated. Do we wish to evaluate primary prevention programs, secondary prevention programs, or combinations of both? If both, which combinations? If the important question is whether treatment at a pre-symptomatic stage reduces morbidity and mortality to a greater extent than treatment at a later stage, then, for example, we might wish to compare primary to secondary prevention programs.

Related to this question is the consideration of whether to evaluate existing programs or broaden the field to new programs or variations of existing programs. Confining an evaluation to existing programs restricts the results from being generalized. This is a concern particularly in STD evaluation, because considerable controversy exists around the best methods to use in prevention programs. When are the most effective times for exposure to prevention programs, and for which groups? Should exposure take place before, during, or after attitudes have formed? Once



they have been formed, how can attitudes be changed? Are we reaching our target population? As claimed by Fors and Devereaux (1979, 26), "evaluation may show insignificant or even negative effects if the health education program is based on inadequate learning theory or determination of educational needs ... Even when the learning theory is adequate and the curriculum well thought out, if the actual teaching process is faulty or if the entire program is not implemented adequately, the results we are hoping for may not appear."

## **Co-Intervention and Other Contamination Problems**

STD evaluation is plagued with problems of co-intervention and other contamination problems. This is especially true of primary prevention programs. To evaluate the effectiveness of a school-based safe sex program, it is difficult (if not impossible) to control for other factors such as parental and peer influence or mass media campaigns. When evaluating a pregnancy prevention program, for example, Zabin et al. (1986) found a seven-month delay in first intercourse among high school students and attributed it to the accessibility of the clinic and staff rather than new information about safe sex.

Controlled experimental designs may be the only way to account for contamination influences. The key issue is whether existing information can be used or whether new studies are required. Existing information could be input into a before/after study design. After carefully controlling for as many factors as possible, a clearly identified STD program could be evaluated. The incidence of disease in that area could be compared against other areas, and conclusions could be drawn on the cost-effectiveness, for example, of that particular program. The difficulty lies in attempting to control for the factors that change over time. For example, for whatever reason, a fundamental change in attitudes or knowledge in that region may have occurred over time. Even if possible, the issue of whether the evidence on effectiveness from that region can be generalized to other regions needs to be addressed. The answer to whether a controlled before/after study design is feasible for STD evaluation cannot be found without an in-depth look into regional programs and other external influences.

If existing information cannot be used, then a controlled experimental design, such as a randomized controlled trial, may be the only way to minimize co-intervention and other contamination problems. With this approach, representative samples of the target populations are randomly assigned to control and experimental groups. Before and after measurements of attitudes, behaviours, and disease incidence are taken to measure the effectiveness of the program. The random assignment to control and experimental groups in each region helps to control the problems typically found in before/after study designs. The drawbacks, of



course, are ethical concerns and the enormous expense and time required to complete randomized controlled trials.

## **Etiology of STDs**

Regardless of the study design used for the evaluation, unravelling the etiologic relationships between STDs, PID, infertility, and other chronic diseases and conditions is complex. Multiple disease incidence, problems in follow-up, wide variations in treatment protocols, imprecise diagnoses, false positive and false negative diagnostic results, and the unreportable nature of most STDs all contribute to the complexity of STD etiology. Compounding these problems is the lag in time between microbial agent infection and its impact on acute and chronic disease. This often lengthy time lag not only obstructs understanding of STD etiology, but also makes study design and patient follow-up difficult.

## **Lack of Standardization in Program Content, Administration, and Implementation**

One of the most frustrating exercises in STD research in Canada is trying to get information on which STD programs are available, who the target groups are, what level of government or organization administers them, what national standards or guidelines are available, and what the content of each program is. The difficulty is largely because STD prevention programs are not coordinated between the federal or provincial levels, except perhaps for AIDS. Most of the federal or provincial statements available are too broad. Therefore, which programs are available, and how they are administered and implemented, varies widely between regions and provinces. In Ontario, for example, STD education is included in the curriculum of each school. The material itself, and how and when it is to be taught, varies by school and school board; no specific provincial standards or guidelines have been established.

Without a better understanding of the full range of programs available, issues such as total cost and the extent of co-intervention and contamination cannot begin to be examined.

## **Collection of Direct Cost Information**

The number and variety of programs available, and the number of different groups, organizations, and levels of government providing similar programs, suggest that estimating the total cost of primary prevention programs or the cost of specific types of programs (e.g., safe sex) will be problematic. In addition, funds for running these programs likely will come from several sources. Under these circumstances, costs may be hidden within budgets of other programs and services and may be difficult or impossible to separate.

Although likely to be a small component of total costs, determining patient out-of-pocket costs for participation in a program (e.g., transportation, parking) will also present problems. Assumptions could be made, or telephone or mail-out surveys could be used to obtain this information.

### **Collection of Indirect Cost Information**

Related to out-of-pocket expenses is time away from work (productivity losses) as a result of participation in the program. Again, the same method could be used to obtain this information.

### **Collection of Direct Benefit Information**

Once decisions have been made about which programs are being evaluated and what the outcome of each program is, there is the difficult task of placing values on these sequelae. For example, in comparing a safe sex primary prevention program to no prevention program at all, the direct benefits of the safe sex program are treatment and other health care costs averted. But what are the averted costs? How many people will go on to develop PID, infertility, and other chronic diseases and conditions? What is the typical treatment protocol for each of these outcomes? Although international classification of disease (ICD) codes can be used to identify the average number of hospitalized days for some STDs, the information does not exist for others. In addition, what about non-hospitalization protocols? Although Health and Welfare Canada (1988) has published guidelines for the treatment of STDs, we do not know to what extent they are followed. Also, how will we estimate the number and type of physician visits and ambulatory care? All of these questions need to be addressed, and surveys from patients or experts working in the field may be the only way to obtain the information.

### **Collection of Indirect Benefit Information**

Knowing the sequelae of each program helps to estimate some of the productivity gains as a result of averted illness or disability. This is particularly true for hospitalizations where the patient must take time off work. But how much time off work is taken for physician visits and other ambulatory care? Given the ambulatory nature of most treatment, such expenses may be quite large. Surveys of patients may be the only way to obtain reliable information.

## **Discussion**

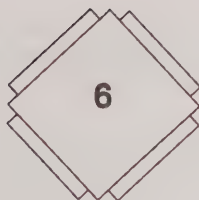
An economic evaluation is an important input into the policy decision-making process. Given the unambiguous objective of STD prevention programs (i.e., cases averted), a CEA is a particularly useful and relevant tool.

Many general screening and prevention programs are not found to be cost-effective compared to other uses of resources. However, given the high cost of associated sequelae and the far-reaching implications of these diseases, STD primary prevention programs may be cost-effective. Even if they are not found to be so, it is likely that target-based programs, such as secondary prevention programs, will be. However, serious methodological issues need to be addressed before such evaluations can be undertaken.

It is impossible to determine whether, and to what extent, some or all of the issues can be resolved. Further research is required to collect all necessary information. Given the lack of standardization and coordination in the administration of STD prevention programs, collecting this information may be quite complex.

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## **Issues in Evaluating Programs to Prevent Infertility Related to Occupational Hazards**

Annalee Yassi



### **Executive Summary**

This paper identifies three sets of issues that must be addressed in examining infertility related to occupational hazards.

First is the knowledge of workplace hazards, which are ubiquitous and difficult to evaluate; even when they have been identified, "safe" levels of exposure for reproductive effects are generally unknown. The author examines strategies to control workplace reproductive hazards. It outlines the hierarchy of control measures, moving from control of the hazard at the source, to control of the hazards along the path, and, as a last resort, control at the personal level. Reducing the possibility of exposure to the risk factor is viewed as the preferred option.

The second set of issues is related to the diversity of prevention strategies that a prevention program may adopt. The study notes that existing prevention programs targeted at reducing exposure to risk factors are not designed specifically to prevent infertility, but have a broader focus. The author points out that reproductive health hazards have unique features that require attention, including differences in male and female physiology, the particular susceptibility of the fetus to agents that pose no serious threat to the adult worker, and the specific



demands of pregnancy. She warns, however, that focussing on the differences between male and female physiology has often led to discriminatory policies that are not well supported by scientific literature.

The third set of issues concerns the evaluation of programs to prevent infertility related to occupational hazards. The study examines issues and methods in evaluating such programs, including evaluation measures, outcome measures, and behavioural measures.

Finally, the study provides a recommended methodological approach for assessing the effectiveness of existing prevention programs.

## Introduction

Before summarizing the issues related to evaluating programs to prevent workplace causes of infertility, some background is provided on the issues in each of the three components of this task: (1) workplace causes of infertility; (2) prevention strategies for controlling reproductive hazards; and (3) program evaluation methodology.

## Workplace Reproductive Hazards

### *Workplace Hazards Are Ubiquitous*

Adverse reproductive outcomes occur often in Canada, yet little is known about the causes of most of these disorders. Although such factors as nutritional status, drug use, smoking, alcohol use, infectious diseases, and demographic and hereditary factors are all known to be important determinants of reproductive outcome, for most infertile couples, no etiology is apparent, raising the possibility that occupational exposures may be responsible or contributory. Most Canadians spend a large portion of their lives in workplaces. Several well-documented situations in which occupational exposures are known to have resulted in deleterious reproductive effects and many reproductive hazards are known to exist in a wide variety of workplaces across Canada. The need for programs to prevent occupationally induced infertility should not be in question.

The vast variety of occupational exposures that affect fertility includes chemical agents (e.g., dibromochloropropane [DBCP] and other chlorinated and non-chlorinated organic solvents; heavy metals such as cadmium, mercury, and lead; and glycol ethers), physical agents (e.g., ionizing and non-ionizing radiation, heat, vibration), biological agents (e.g., rubella, cytomegalovirus, *Toxoplasma*), ergonomic factors (e.g., prolonged standing, physical workload), and psychosocial stressors. Both men and women are subject to exposures that may affect reproduction. Moreover, workers are seldom exposed to only one occupational hazard; several such hazards may be present, or may be superimposed on non-occupational factors, to produce a negative reproductive outcome.

### ***Workplace Reproductive Hazards Are Difficult to Evaluate***

Considerable uncertainty exists regarding the exact type and extent of occupational reproductive hazards. Basically, four methods can detect such hazards.

1. Observational epidemiology is a method wherein workers, astute clinicians, or other individuals or groups observe relationships that lead to the identification of reproductive hazards. Perhaps the most famous example is that of DBCP, which was discovered as a reproductive toxin when five workers from a plant manufacturing the chemical agent noted the low birth rate among workers in the plant and reported voluntarily for evaluation of infertility. Their markedly reduced sperm count and similar levels in other exposed workers were subsequently demonstrated to be associated with duration and extent of exposure to DBCP.
2. Analytical epidemiological investigations are the most powerful tool in evaluating occupational hazards. Such studies are designed to assess the relationship between exposure and reproductive outcome; however, they have methodological problems regarding sample selection and use of appropriate comparison groups, inadequacies in exposure characterization, difficulties in the determination of outcome, and problems in data analysis. These weaknesses are discussed in many texts and review articles, including one by Rosenberg, Feldblum, and Marshall, who have compiled a list of the English-language articles on occupational reproductive disorders published in the medical literature from 1981 to 1985.<sup>1</sup>

As noted in the many publications discussing methodological difficulties in studying reproductive disorders, a variety of reproductive outcomes can be measured, but reliable and easily detectable negative outcomes of interest are usually relatively rare. The number of live births required to detect a twofold increase in the rate of all major birth defects, for example, is 316 (Table 1). In a study of a single workforce, it is quite unlikely that a sufficient number of births would occur. In general, most studies in this area have inadequate sample sizes, poor response rates, selection bias, inadequate attention to potential confounders, and insufficient characterization of exposure. However, some important work of high quality has managed to emerge in Canada and elsewhere: for example, the work of McDonald et al.<sup>2</sup>

3. Information regarding reproductive toxicity can be derived from animal studies; however, they too have difficulties. Even when great attention has been paid to the methodology of such studies, debates as to the applicability to humans or the validity of extrapolating high-dose animal tests to much lower-dose human exposures persist. At least 50 chemicals have been shown to cause reproductive impairment in animals; however, relatively few workplace hazards have been studied regarding their reproductive effects. For those that have, usually only

one or two reproductive outcomes have been investigated, leaving uncertainty about the remaining reproductive outcomes.

4. Surveillance is defined as "the continued watchfulness over the distribution and trends of incidents through the systematic collection, consolidation, and evaluation of morbidity and mortality reports and other relevant data" (e.g., birth defect monitoring programs). Several such systems exist in various countries. As cases are identified in the surveillance process, analytical epidemiological studies could be performed on such data bases with considerably reduced costs compared to newly initiated ones. However, problems exist with surveillance for infertility, particularly about what outcome to study. The completeness of ascertainment is important in surveillance systems. Studying events such as birth, for which medical attention is essentially universal, is relatively easy. Monitoring of spontaneous abortion is much more difficult. The likelihood of a woman seeking medical attention for problems of pregnancy increases with the length of gestation; for example, New York's surveillance system includes all pregnancies that extend beyond 28 weeks. However, since less than 10 percent of spontaneous abortions occur later, such a system is limited. Similarly, reliable monitoring of infertility is difficult because of the unpredictable likelihood of seeking medical evaluation and the lack of standardized reporting.

**Table 1. Sample Size Required to Detect a Doubling of Background Incidence in Reproductive Outcome\***

Reproductive outcome size of each group required	
Infertility	161 couples
Spontaneous abortion	161 pregnancies
Stillbirth	161 pregnancies
Low birth weight	293 live births
Major birth defects	316 live births
Infant deaths	928 live births
Severe mental retardation	4 493 live births
Chromosome abnormalities	8 951 live births

\* Alpha = 0.05, two-tailed; Beta = 0.20.

**Source:** U.S. National Institute for Occupational Safety and Health, *Proposed National Strategy for the Prevention of Disorders of Reproduction* (Cincinnati: NIOSH, 1988), 7.



### ***“Safe” Levels of Exposure Not Known***

Even for hazards that have been studied and assigned occupational exposure limits or threshold limit values (TLVs), these levels seldom consider reproductive effects. The TLV guidebook<sup>3</sup> notes that these levels were set to protect most of the workforce, but may not be protective for particularly susceptible groups (presumably the fetus is such a group). Thus, to mount a comprehensive program to decrease occupationally induced infertility would require considerably improved testing requirements of potential hazards and research into this area.

## **Strategies for Controlling Workplace Reproductive Hazards**

### ***Approaches to Prevention***

Strategies to prevent deleterious outcome are varied. Most health care dollars targeted to prevention in general are spent on secondary prevention (detecting negative outcome early enough to treat it effectively and implement further prevention measures) or tertiary prevention (minimizing the effect of the negative outcome). However, it is most effective in implementing primary prevention measures (preventing negative consequences by addressing the cause, before any effects occur).

Primary prevention may be active or passive. Active prevention requires individuals to change a behaviour or take other active measures. In contrast, passive prevention measures are taken systemically. Substituting a relatively innocuous substance in the place of a highly toxic one is an example of passive prevention, whereas educating people to wear masks and gloves when handling toxic substances is active prevention. Legislative changes lowering allowable exposure levels are usually considered passive measures, as, presumably, no decision whether or not to comply needs to be taken by the individual.

In occupational health the hierarchy of effectiveness of control measures are (1) control at the source (e.g., substitution, process changes that eliminate harmful exposures); (2) control along the path (e.g., barriers, enclosures); and (3) only as a last resort, control at the person (e.g., personal protective equipment such as masks and gloves). Workplace programs that focus on eliminating hazards at the source are preferable.

### ***Steps to Control Reproductive Hazards***

The identification of a potential reproductive hazard either by observation, epidemiological study, toxicological experiments, or medical surveillance should prompt a workplace assessment to ascertain the extent to which the hazard is present. This usually involves industrial hygiene monitoring. Once actual risk to workers is evaluated (or, at least, risk of exposure, as risk of outcome is difficult to assess without dose-response relationships), a program needs to be implemented that involves establishing corporate policies and procedures, education of workers regarding the potential hazard and protective measures required, and, preferably,



engineering controls to minimize worker exposure. These actions are no different from those used to control other hazards in the workplace. Also, exposures that impair reproductive function usually have other toxic properties; reproductive toxicity is just one of the reasons necessitating control measures. These hazard control programs are often not specific to reproductive hazards.

### ***Unique Characteristics of Reproductive Hazards***

Reproductive health hazards have unique features that require attention. They include differences in male and female physiology, the particular susceptibility of the fetus to teratogens (a factor or agent that poses no serious threat to the adult worker), and the specific demands of pregnancy.

Focussing on the differences between male and female physiology has often led to discriminatory policies, which were not well supported by scientific literature.

Courts have concluded that policies that target fertile or pregnant women are sex-discriminatory even if the purported reasons were related to health protection, except under limited circumstances. The evidence that would have to exist to allow exclusionary policies aimed specifically at pregnant women includes (1) that the exposure poses a significant and unreasonable threat to the fetus (not a speculative risk); (2) that the exposure at hazardous levels is likely to occur; (3) that the risk is confined to exposures of women (i.e., the male reproductive system is not similarly susceptible); and (4) that a substantial body of experts supports these conclusions to the extent that "an informed employer could not responsibly fail to act."<sup>4</sup> The policy must not be a pretext for discrimination. It is noteworthy that fetal protection policies have been invoked in male-dominated workplaces, while often the better-known reproductive hazards in female-dominated occupations have not led to such policies.

An otherwise justifiable policy would be unacceptable if an alternative would provide protection without being discriminatory. The Canadian labour movement adamantly insists that workplace hazards be controlled to levels that are safe for all workers, even the more susceptible ones.

### ***Medical Removal or Protective Reassignment of Pregnant Women***

In some workplaces and jurisdictions, protective reassignment during pregnancy has been implemented. In these situations, pregnant workers are given the option of alternative work, without loss of seniority, benefits, wages, or the right-to-return to the original job. Some workplaces only provide transfers during pregnancy "if feasible" or "if alternative work is available." In other workplaces or jurisdictions, when alternative work is not available, the pregnant worker is moved out of the workplace without penalty (Quebec legislation follows such an approach).

### ***Possible Government, Industry, or Workplace-Based Initiatives***

As noted previously, the best program is one that aims to eliminate or reduce hazardous exposures at the source. Labour organizations in Canada have repeatedly called on governments to require thorough testing for all reproductive effects on all workplace materials, and have proposed the development of a generic reproductive hazard standard that provides criteria by which reproductive hazards are identified and control programs are promptly instituted in Canadian workplaces. Labour groups insist that where this is impossible, reproductive medical removal protection must come into effect wherein any woman or man attempting to reproduce can choose to be moved out of exposure with full wage and benefit protection.<sup>5</sup>

## **Program Evaluation — Methods and Issues**

### ***Goals of Evaluation***

Program evaluations are usually conducted either (1) to provide information to the appropriate decision makers/funders so that it may be determined whether to continue, increase, or withdraw support for the program; or (2) to provide information to the program providers so that they may improve the effectiveness of the program; or (3) to provide an opportunity for the target population or clients of the program to indicate whether they are satisfied that their needs are being met.

For decision makers/funders an evaluation should answer the following questions: Is (was) there a need for the program? Is the program addressing the need for which it was designed? Is it addressing other needs? Is the program successful in meeting its objectives (is it "effective")?

Usually decision makers/funders are interested in whether the program is cost-effective. It is useful to ask whether the expense of the program compares favourably with alternative ways of providing the service. A cost-benefit analysis can also be conducted to determine if the money saved as a result of the program is greater than the cost of the program.

Decision makers and program providers are interested in an evaluation that determines whether the program is managed optimally (are all components cost-effective?) and whether changes could be made to make its operation more effective and efficient.

Finally, it is necessary to evaluate whether the recipients of the program perceive it as meeting their needs and are satisfied with the service provided (acceptance and satisfaction).

### ***Study Design Issues***

In general, evaluations should be conducted so that they do not disrupt the program. A formal evaluation should be conducted by an outsider who has an objective viewpoint. As much objective data as possible should be used and any potential biases should be recognized before conclusions are drawn. Input should be sought from all interested parties on all aspects of the evaluation.

The criteria to be used must be clearly specified before the evaluation begins. The basic methodology of evaluation is to compare the program's experience to a benchmark, usually that of the immediate past; a comparison group; predicted results; or reasonable expectations (standards, if they exist). The comparison between the benchmark and the program's experience is facilitated by statistical analyses to take into account random error and variability.

The closer the evaluation methodology is to an experimental design, the less it is subject to bias. Ideally, the outcome of interest in the experimental group that received the program should be compared to that of an appropriate control group that did not. This often is not possible in occupational health for ethical or practical reasons, unless the program was designed specifically to include research into its effectiveness. As most programs are provided as services, not research, evaluation often must be based on a comparison with a group that is not identical but matched as closely as possible to the program's targeted group. Alternatively, a before/after comparison can be made within the target population. Preferably a combination of both can be used: the experience in the target group is compared to that in the group not offered the program, both before the program begins and afterwards. Using a comparison group is particularly important when changes may be occurring over the course of the program that do not relate to the program (e.g., changes in the incidence of the outcome measure in the community, in education and public attitudes, in the composition of the workforce). Differences between the comparison group and the target population must be considered.

### ***Evaluation Measures***

The validity of the study design is only one methodological consideration; the data collected also must be accurate and the measurement meaningful. The decision as to which variable or set of variables is a good measure of the effectiveness of a program depends on the setting and goal of the program. Four categories of variables generally exist:

#### ***Outcome Measures***

These variables should be quantifiable and accessible; the data used must be accurate and valid. (Examples of typical outcome used in occupational health evaluations include the incidence of injury, cost to employer per employee per component of the program, etc.)

#### ***Behavioural Measures***

These variables measure whether individuals have changed risk behaviour as a result of the program. (For example, is there better compliance with safety procedures?)

#### ***Criteria Measures***

The program could be evaluated to see if it meets specific operating criteria. (For example, is exposure monitored regularly? Are exposure levels in keeping with accepted criteria?)



### *Satisfaction Measures*

These variables assess worker and employer satisfaction. (Methodology for this measure may include key informant interviews, questionnaires to the workforce, etc.)

## **Summary**

The first set of issues that must be addressed relates to knowledge of workplace reproductive hazards. Reproductive hazards are ubiquitous in Canadian workplaces, and these hazards may interact with non-occupational factors to cause infertility. Both men and women are subject to exposures that may cause infertility. Most important, workplace reproductive hazards have not been well researched; thus, the type and extent of deleterious effects on reproduction that can be caused by certain occupational exposures is largely unknown. Even for hazards that have been well recognized for many decades, safe levels of exposure with respect to reproductive outcome are largely unknown.

The second set of issues relates to the diversity of prevention strategies that a particular program may adopt. Some programs aim at early identification of reproductive problems (secondary prevention) or attempts at treatment of this infertility (tertiary prevention). However, the best strategy for controlling workplace reproductive hazards is usually primary prevention, which focusses on eliminating the hazards at the source. The steps involved in this activity are no different than those used to control other hazards in the workplace, and many reproductive hazards are controlled by general occupational hazard control measures not aimed specifically at the reproductive toxicity of certain substances. In other situations, programs to prevent occupationally induced infertility have focussed on particularly sensitive workers such as pregnant women. Considerable controversy has arisen about such programs, with allegations of discrimination receiving prominent media attention. The male reproductive system is as sensitive, and sometimes more sensitive, than the female reproductive system, thereby undermining potential scientific rationalization for such policies. In evaluating programs aimed at preventing workplace-induced infertility, human rights and ethical issues must figure prominently.

Programs may be initiated at the national, provincial, industry-wide, or workplace levels. The evaluation strategies for programs mounted at the different levels would vary considerably.

Many issues need to be considered to evaluate programs aimed at preventing work-related infertility. The goals for the evaluation must be abundantly clear. It must be decided whether it will be an effectiveness evaluation, a cost-effectiveness evaluation, a cost-benefit evaluation, or a quality assurance exercise. The benchmark to be used in the evaluation



must be decided (i.e., whether comparisons will be made to the experience of the target population before the program begins, whether or not a comparison group will be employed). Perhaps the most difficult issue in evaluating workplace programs to prevent infertility is the choice of evaluation measure. Ideally, one would like to measure whether a program is effective in changing negative outcome; that is, whether or not infertility has been reduced. Such an exercise is difficult at the workplace level, as the sample size required to find a statistically significant difference in successful healthy births is usually greater than the size of the workforce allows. Measures such as birth defects, congenital anomalies, spontaneous abortions, and low birthweight can be used if evaluation is conducted provincially or nationally, or in an industry in which the number of workers is very large and the cohort could be easily identified. Surveillance systems are of assistance in facilitating such studies.

When evaluating workplace programs, it is usually best to focus on process measures, particularly on criteria measures that indicate whether the procedure used in the program meets with its accepted occupational health guidelines.

As the workforce and worker representatives may not have the same perspective as management, it is essential that any occupational health evaluation of a program in this area includes worker/union input at all phases of planning and implementation.

## **Recommended Methodological Approach for Assessing the Effectiveness of Existing Prevention Programs**

The methodological approach to adopt will depend on the type and setting of the program to be evaluated. For instance, the effectiveness of government policies (e.g., whether the Quebec legislation has resulted in more effective prevention of occupationally induced infertility than in provinces that have no such legislation) would obviously require a different methodology than an evaluation of a workplace-based program. No one evaluation strategy could be adopted for all purposes and programs.

At the national or provincial levels, it can also be ascertained if infertility surveillance programs exist, and methods can be adopted to evaluate the effectiveness of such programs with respect to occupational hazards. The evaluation methodology most appropriate for a surveillance system likely would focus on process, particularly criteria measures and satisfaction measures, rather than on assessing whether the system has resulted in a change in actual reproductive outcome. The appropriateness of the measures recorded by the surveillance system (e.g., major birth defects, spontaneous abortion, perinatal death, birthweight) should be evaluated, particularly with respect to their validity, accuracy, and the completeness of ascertainment. The comprehensiveness and accuracy of

the independent (e.g., demographic and other risk profile) variables collected should be determined also. Perhaps most important, the extent to which the data base is used to evaluate trends and identify reproductive hazards should be assessed; and, if it is not well used, the evaluation should attempt to elucidate why. The principles of evaluation discussed in the section entitled "Program Evaluation — Methods and Issues" should be applied.

At the workplace level, an evaluation could be conducted to determine the effectiveness of occupationally induced infertility prevention. Again, a criteria-based and satisfaction-based approach would be recommended, because an evaluation of fertility outcome is complicated and costly, and will likely be inconclusive. Behaviour outcome can be included in the evaluation (e.g., are the workers using the personal protective equipment recommended? are safe handling techniques used?).

Usually, the process measures to be evaluated would address the following:

- Has a survey been conducted to identify substances or conditions that have a potentially adverse effect on reproduction?
- Has the scientific literature regarding potential hazards been consulted to appraise the risk?
- Have protective measures been developed?
- Is the workplace monitored regularly?
- Has corporate policy been developed to prevent exposure in particularly vulnerable groups? Is this policy well founded scientifically, non-discriminatory, and respectful of human rights? Is there a well-developed procedure to facilitate transfer to alternative employment, if necessary?
- Is the workforce provided with adequate training with respect to these hazards and the appropriate control measures?
- Is there a procedure to ensure that new employees are made aware of these hazards, the controls, and their rights?
- Is occupational medical expertise appropriately used to counsel employees and document relevant reproductive histories?
- Is there systematic follow-up of reproductive disturbances and pregnancy outcome in areas identified as potentially at risk?
- Is the joint (labour/management) health and safety committee fully involved in designing policies and procedures?
- Does the health and safety committee receive reports?

The evaluation should be conducted by outside experts, and both worker and management perspectives obtained on each issue. While questionnaires can be used to test knowledge, attitude, and behaviour

regarding various risk factors, interviews with key personnel (union and management) would be advisable also.

Specific evaluation strategies would have to be formulated to address specific programs. The extent of such programs in Canada, either nationally, provincially, industrial-sector-wide, or in specific workplaces, is not known. Further research in this area would be required before specific evaluation strategies could be recommended.

## Notes

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2. A.D. McDonald et al., "Occupation and Pregnancy Outcome," *British Journal of Industrial Medicine* 44 (1987): 521-26.
3. United States, National Institute for Occupational Safety and Health, *Proposed National Strategy for the Prevention of Disorders of Reproduction* (Cincinnati: NIOSH, 1988).
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5. Canadian Union of Public Employees, "Our (Reproductive) Health Is Not for Sale — The Role of the Workplace in Adverse Reproductive Outcomes," Presentation to the Royal Commission on New Reproductive Technologies (Toronto, 20 November 1990).

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# **The Integration of Theoretical Approaches to Prevention: A Proposed Framework for Reducing the Incidence of Infertility**

Brian Hyndman, Alyssa Libstug, Irving Rootman,  
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## **Executive Summary**

This report, prepared by a multidisciplinary team of researchers from the Centre for Health Promotion, Faculty of Medicine, University of Toronto, reviews the literature on the prevention of male and female infertility. The primary objective of this review was to assess whether various models of primary and secondary prevention could be used to modify the risk factors related to infertility.

A literature search identified seven primary risk factors for infertility: sexually transmitted diseases, contraception, obesity, exercise, smoking, substance abuse (including alcohol), and occupational or environmental hazards.

The three main types of frameworks examined were individual behaviour models, group intervention models (which focus on communities or target populations, rather than individuals), and prevention target models (which focus on specific behaviours or factors). Each of these has certain aspects that would help modify the risk factors in infertility, but none is appropriate on its own, possibly because the



risk factors are so wide-ranging. Preventive interventions must address both the behavioural (individual) risk factors (sexual behaviour, contraception, weight, diet, exercise, social interaction) and the environmental risk factors (workplace hazards, community hazards, socioeconomic factors).

Because no single one of these models is appropriate, the useful aspects of each were combined to develop a new, comprehensive model for changing the risk factors related to infertility. This model lists the barriers to change and the enhancers of change. It outlines which types of interventions are appropriate at the behavioural level, and which at the environmental level. These interventions include community organization, social marketing, education and training, preventive programs and services (e.g., dispensing condoms, or screening of high-risk occupational groups), policy or legislative measures, and incentives for individual change and group compliance (e.g., recognition for safe worksites).

To increase the potential power of the framework, recommendations were also made on research priorities, epidemiological monitoring, workplace prevention measures, and community prevention measures. Finally, the legal, ethical, and economic issues uncovered through the review are noted.

## Introduction

The prevalence of infertility worldwide does not appear to be on the rise: the incidence of this condition has remained relatively stable, affecting five to seven percent of reproductive-aged couples in the industrialized world. Complications arising from preventable conditions — such as sexually transmitted diseases (STDs), post-abortion and post-partum infections, and environmental contaminants — are viewed as significant risk factors for these cases (Ashley 1987; Stillman et al. 1986).

Clinical treatment (tertiary prevention) of infertility is seldom effective. Moreover, because such services are costly and are available only in certain areas, they are inaccessible to most people. The early identification of infertile individuals through screening, which might allow secondary prevention, is difficult. Therefore, primary prevention of the related risk factors appears to be the most expedient approach to reducing the incidence of infertility.

This report, written by a multidisciplinary team of researchers from the Centre for Health Promotion, University of Toronto, reviews the research literature on primary and secondary prevention in order to identify models of prevention. The applicability of these models in modifying risk factors is also assessed.

The report consists of five main sections. The initial section describes the methods of gathering information, including the data bases examined and the prevention experts consulted. Working definitions of primary

prevention, secondary prevention, and health promotion are also provided. The meaning of the term *model* and the types of models we examined are also included in this section.

The models of primary and secondary prevention reviewed are introduced in the second section of the report. Each model is discussed in a separate subsection, which contains a description of the model, a critical appraisal of its strengths and limitations, and a review of studies applying the model to the following categories of infertility-related risk factors: contraceptive use and STD prevention, weight control and exercise, and smoking and other drug use. The sample size of each study cited in this section, as well as the sociodemographic characteristics of each respondent population, is provided in Appendix 2.

In the third section, approaches to preventing exposure to occupational and environmental risk factors related to infertility are outlined. This topic is addressed in a separate section, since the methods of preventing workplace and environmental hazards differ substantially from the methods applied to the other risk factors.

The fourth section of the report discusses which models or approaches should or should not be considered when designing interventions to prevent infertility. A step-by-step framework, or template, is also presented. This framework can be used to determine which models, or components of models, are most appropriate for preventing each infertility-related risk factor in a particular priority group.

The final section of the report contains recommendations addressing the following issues: what strategies appear to be most appropriate for the prevention of infertility; priorities for future research; and the societal implications of approaches to prevent infertility, including legal, ethical, and cost considerations.

## Methods, Concepts, and Definitions

### Information-Gathering Methods

A series of literature searches covering the period from 1975 to the present was ordered from the Addiction Research Foundation and the University of Toronto. The MEDLINE, POPLINE, BIOSIS, ERIC, PsycINFO, Sociological Abstracts, and CCHS data bases were scanned to identify studies applying models of primary and secondary prevention to the following infertility-related risk factors: sexually transmitted diseases, contraceptive use, obesity, exercise, smoking, substance abuse, and occupational or environmental hazards. Several hundred references were generated from these searches. An additional 150 references were collected using the snowball technique.

Advice and information was also obtained from researchers and consultants familiar either with the risk factors related to infertility or with

approaches to prevention in general. A list of the persons contacted is provided in Appendix 1. Several of the individuals served on an expert resource group, which provided feedback and guidance.

## **Key Concepts and Definitions**

For the purposes of this investigation, the following concepts and definitions were adopted.

### ***Health Promotion***

Health promotion is defined as the "process of enabling people to increase control over, and to improve, their health" (International Conference on Health Promotion 1987). This widely accepted definition of health promotion represents a participatory strategy aimed at the population and their total environment (Stachtchenko and Jenicek 1990).

### ***Primary Prevention***

Primary prevention seeks to reduce/prevent the likelihood that a disease or disorder will develop in a person. The three main approaches at this level of prevention are modifying the host to reduce susceptibility (e.g., immunization); reducing exposure to, or removing, environmental risks; and health promotion (Shah 1990). There are, however, a number of conceptual differences between health promotion and primary prevention strategies (see Stachtchenko and Jenicek 1990, for example).

### ***Secondary Prevention***

Secondary prevention is the detection and early treatment of disease before irreversible damage has occurred. Unlike health promotion and primary prevention, health agencies and health professionals play a dominant role in the provision of secondary prevention services (Shah 1990). Screening — that is, the identification of unrecognized pathologies through tests or other procedures — is one of the techniques most widely used in secondary prevention.

### ***Models of Health Promotion and Disease Prevention***

The models of health promotion and disease prevention considered in this review are simplified descriptions that help predict an individual's exposure to infertility-related risk factors or that help in the design of interventions aimed at modifying or eliminating these factors. The models considered in this report fall into three main categories: individual behaviour models, group intervention models, and prevention target models.

#### ***Individual Behaviour Models***

The Health Belief Model (Rosenstock 1974), the Theory of Reasoned Action (also known as the Theory of Planned Behaviour) (Ajzen 1985), and the Social Learning Theory (Bandura 1977) are classified as individual behaviour models. These models focus on explaining and predicting the health-related attitudes and actions of individuals.



### **Group Intervention Models**

Group intervention models focus on populations and communities, rather than individuals. Social Marketing (Kotler and Zaltman 1971), the Diffusion of Innovations Theory (Rogers 1983), and the PRECEDE Model (Green et al. 1980) are approaches to facilitating preventive or health-promoting activities in identified priority groups. Models of community mobilization, by contrast, foster collective actions aimed at addressing health hazards in the social or physical environment. All these models are premised on theories of social change.

### **Prevention Target Models**

Prevention target models are more limited in scope than the other theoretical frameworks considered in this report; they identify priorities or targets for prevention, but do not address the process of program implementation or the content of interventions. The AODAM Model (Shain et al. 1991), Sociostructural theories of health and illness (McKinlay 1981; Noack 1988), the Socioenvironmental Approach to Health (Toronto, Department of Public Health 1991), and the traditional Epidemiological Triangle (Dever 1980) are discussed as examples of prevention target models.

## **Models of Health Promotion and Disease Prevention**

### **Individual Behaviour Models: Health Belief**

The Health Belief Model was originally developed during the 1950s to explain people's widespread failure to participate in screening programs to detect tuberculosis (Rosenstock 1974). Since that time, the model has become one of the most influential and widely used approaches to explaining and predicting health-related behaviour.

The Health Belief Model maintains that individuals will take preventive measures against a particular disease if they regard themselves as susceptible to the condition (perceived susceptibility); believe that the consequences are potentially serious (perceived severity); believe that the preventive measures available to them would be effective in reducing their susceptibility to or the severity of the condition (perceived benefits); and believe that the costs of taking the preventive measure (perceived barriers) are outweighed by the benefits. Later formulations of the Health Belief Model included the concept of self-efficacy, that is, the belief that one can successfully perform the behaviour required to produce a desired outcome (Bandura 1977).



## ***Applications of the Health Belief Model***

### ***Contraceptive Use and STD Prevention***

Research has yielded partial support for the Health Belief Model as a means of accounting for contraceptive use and other behaviours that prevent STDs.

In a survey of unmarried college students, Lowe and Radius (1987) found that respondents perceived relatively few barriers to their use of contraception. In other words, the benefits of contraceptive use far outweighed the costs or difficulties of use. Similarly, Simon and Das (1984) found a strong association between perceived benefits and the likelihood that university students would take action to prevent or control venereal disease. Perceived susceptibility and perceived barriers also correlated modestly with the likelihood of preventive behaviours.

Condelli (1986) was able to use the Health Belief Model to explain the contraceptive choice of women at a suburban family planning clinic. Women who used oral contraceptives were distinguished from diaphragm users by their belief that the diaphragm was more inconvenient (perceived barriers) and the pill more convenient (perceived benefits). Women who used the pill expressed less concern about the side-effects of the pill (perceived barriers) and believed they were more susceptible to becoming pregnant (perceived susceptibility) when not using the pill.

There is some evidence that the Health Belief Model's ability to predict adolescents' intentions to adopt safer sex behaviours decreases with the age of the respondent (Petosa and Jackson 1991). Such evidence suggests that education promoting safer sex among younger adolescents should focus on health-related motivations, while education aimed at their older peers should address factors directly relevant to their motivational schema and social environment.

A telephone survey of over 1 000 adolescents in Massachusetts revealed that sexually active young people who believe that condoms are effective in preventing HIV transmission (perceived benefits) and worry about contracting AIDS (perceived susceptibility) are significantly more likely to use condoms all the time (Hingson et al. 1990). Respondents who believe that condoms do not inhibit sexual pleasure and who would not be embarrassed if asked to use them (perceived barriers) were also more likely to use condoms.

Eisen et al. (1985) used the Health Belief Model as a conceptual framework for developing a community-based intervention to strengthen the fertility control behaviours of adolescents (i.e., abstinence and contraceptive usage). A longitudinal evaluation of the program revealed that consistent contraceptive use increased significantly, and that 62 percent of the program recipients remained abstinent from before the program to follow-up three to six months later.

### *Exercise and Weight Control*

A large number of studies have used the Health Belief Model to explain compliance to diet and exercise regimens. These investigations have yielded varying degrees of support for the Model's predictive powers.

Becker et al. (1977) studied factors affecting the adherence of low-income mothers to a diet prescribed for their overweight children. Multiple-item scales were used to assess each component of the Health Belief Model before the mothers received instruction from a dietician. Each child's weight change was measured at four follow-up visits spaced two weeks apart. Results indicated that the combined Health Belief Model variables accounted for close to half of the variance in weight changes on the first follow-up visit, but only 22 percent of variance by the final visit. It appears, therefore, that health beliefs may be the most important determinants of compliance at the beginning of a dietary intervention, but that other variables increase influence over time.

Other studies have used the Health Belief Model to explain differences in the dieting and exercise behaviours of physically fit and physically unfit individuals. O'Connell et al. (1985) found that the perceived benefits of dieting were the most powerful predictor of dieting behaviour for obese adolescents, while perceived susceptibility to obesity best explained the eating behaviour of non-obese adolescents. Similarly, Desmond et al. (1990) found that adolescents in good physical condition scored significantly higher on the perceived susceptibility and perceived severity subscales and significantly lower on the measure of perceived barriers. Biddle and Ashford (1988), by contrast, found that sedentary adults had higher levels of perceived susceptibility than their physically active peers. Similar results were obtained by Lindsay-Reid and Osborn (1980).

Studies measuring Health Belief Model constructs underscore differences in the health-related attitudes and behaviours of respondents with different sociodemographic characteristics. For example, analyses of data from the Michigan Blood Pressure Survey indicate that female respondents believe that they suffer more severely from illnesses (perceived severity). Black respondents expressed greater concern about their health (perceived susceptibility). Female, Black, older, and low socioeconomic status respondents exhibited higher levels of perceived benefits, placing greater value on healthy personal habits such as exercise and proper diet (Weissfeld et al. 1990).

### *Smoking and Other Drug Use*

Studies assessing the smoking behaviour of individuals have generally upheld the explanatory value of the Health Belief Model. In a study of 120 current and ex-smokers, Weinberger et al. (1981) found that ex-smokers view smoking as a serious health problem and feel personally susceptible

to its adverse effects. Current smokers also view smoking as serious, but they do not perceive themselves as being susceptible to tobacco-related health problems.

Strecher et al. (1985) assessed beliefs about susceptibility to health problems (both for smokers and non-smokers) in a group of over 200 patients at a veterans' hospital. Difficulty in resisting urges to smoke, an indicator of perceived barriers, was also measured. Neither perceived susceptibility nor a perceived barrier was directly related to a reduction in smoking three months later. The interaction of the two measures, however, was a significant predictor, with high susceptibility plus low perceived difficulty yielding the greatest reduction.

Research using the Health Belief Model to account for alcohol consumption is sparse. Respondents enrolled in an alcoholism treatment program exhibited higher levels of perceived severity than a sample of problem drinkers not in treatment (Bardsley and Beckman 1988). Beck (1981) found a positive correlation between Health Belief Model constructs and drinking and driving behaviour of a group of college students.

### ***Strengths and Limitations of the Health Belief Model***

Over three decades of research have provided substantial empirical support for the Health Belief Model, with findings from prospective studies at least as favourable as results obtained from retrospective investigations (Janz and Becker 1984). Perceived barriers are the most accurate predictor of behaviour across all studies.

In spite of its proven explanatory powers, a number of critiques have emphasized the following inter-related shortcomings of the Health Belief Model: the belief-behaviour relationship has never been uniformly established; direct attempts to modify beliefs are often unsuccessful; and social and environmental factors may deter individuals from taking their preferred course of action (Rosenstock 1990). For these reasons, critics of the Health Belief Model argue that interventions aimed at modifying the environment will likely prove to be more effective than attempts to modify the belief systems of individuals.

Rosenstock (1990) acknowledges that permanent changes in behaviour can rarely be accomplished by efforts to modify belief systems alone, but he cautions against disregarding the importance of intrapersonal factors in shaping health-related behaviours. Cognitive factors, such as health beliefs, have minimal influence on entrenched habitual behaviours. However, they have greater influence when signals for change (e.g., distress symptoms) are noted. When behavioural change is contemplated, health beliefs may guide behaviour, as well as be modified by the effort (Kirscht 1983, 1988). Changes in beliefs, therefore, are required in efforts to achieve behaviour change, and the importance of understanding the impact of belief systems on health-related behaviours should not be overlooked.



## Individual Behaviour Models: Theory of Reasoned Action

The Theory of Reasoned Action (Fishbein 1967; Fishbein and Ajzen 1975) can be used to explain any behaviour over which an individual has volitional control. The theory assumes that behavioural intention is the immediate determinant of behaviour. The strength of an individual's intention to perform a specific action is a function of her or his attitude toward the action and the influence of general subjective norms. Attitude is determined by an individual's belief that a given outcome will occur if the action is performed, and by an evaluation of that outcome. Subjective norms are determined by an individual's normative beliefs about what others think she or he should do and by an individual's motivation to comply with the wishes of those others (Figure 1).

Ajzen (1985) revised the Theory of Reasoned Action in recognition of the fact that there are a limited number of behaviours over which an individual has volitional control. The modified version of the model, known as the Theory of Planned Behaviour, notes that there are many situations when behavioural intention can predict only an individual's attempt to perform a behaviour; actual performance is a function of individual effort and volitional control.

The original Theory of Reasoned Action is an accurate predictor when the degrees of volitional control and individual effort are high, but the Theory of Planned Behaviour provides a better explanation when the degree of volitional control and the probability of success are low. At present, only a few studies have used the Theory of Planned Behaviour to account for health-related actions.

### ***Applications of the Theory of Reasoned Action***

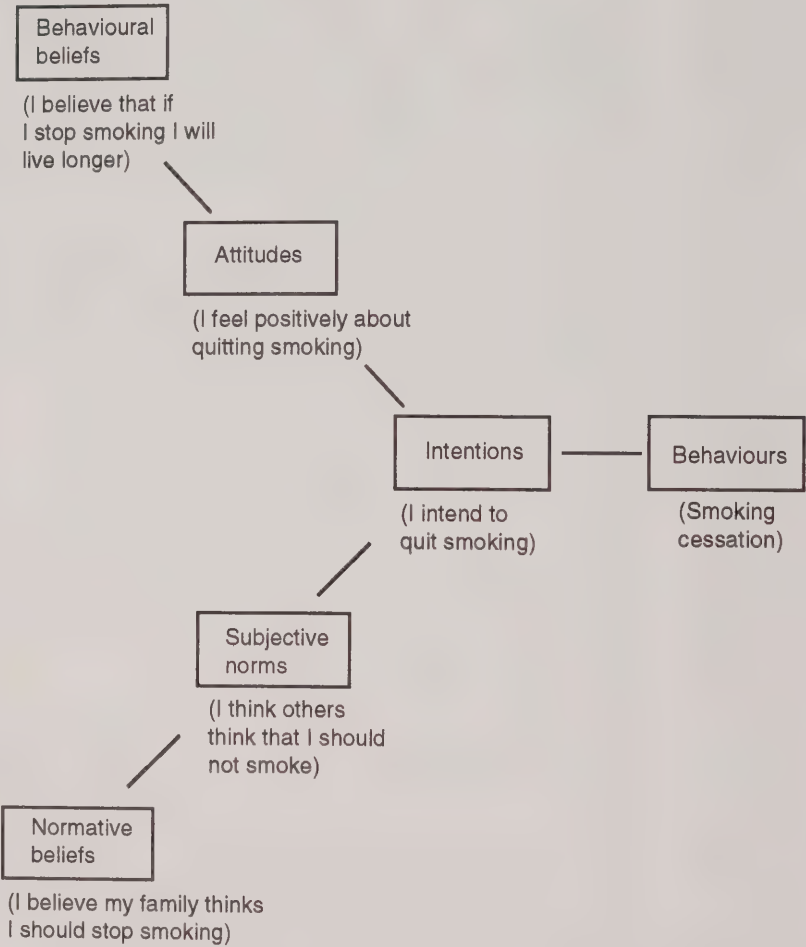
#### *Contraceptive Use and STD Prevention*

A number of studies have applied the Theory of Reasoned Action to sexual decision making, including contraceptive use. Individuals' attitudes and subjective norms account for a high proportion of the variance in their intentions concerning contraceptive methods. For example, attitudes and norms accounted for 79 percent of the variance in intentions to use birth control pills among college students (Jaccard and Davidson 1972) and 74 percent of the variance for married women (Davidson and Jaccard 1975). Attitudes and subjective norms were used successfully to predict intentions to use condoms among a group of patients at a STD clinic (Baker 1988).

Werner and Middlestadt (1979) used the Theory of Reasoned Action to examine oral contraceptive use in a group of sexually active female college students. Both attitudes and subjective norms were significantly related to the use of birth control pills; a stronger relationship was obtained when both components of the theory were combined. Non-users were more likely to link birth control pills with unhealthy consequences, while users



**Figure 1. The Theory of Reasoned Action**



**Source:** M. Fishbein and I. Ajzen, *Beliefs, Attitudes, Intentions and Behavior: An Introduction to Theory and Research*. © 1975 by Addison-Wesley Pub. Co. Reprinted by permission of Addison-Wesley Publishing Co. Inc., Reading, Massachusetts.

believed that employing this method of contraception enhanced their sexual satisfaction.

Research has also assessed the efficacy of interventions designed on the Theory of Reasoned Action principles. In one study, users and non-users of contraceptives were exposed to messages advocating one of three contraceptive techniques: males were advised to use condoms; males were advised to rely on their partners' use of contraceptives; and females were advised to use oral contraceptives (McCarty 1981).

Results provided moderate support for the Theory of Reasoned Action, as the messages induced changes in attitudes and intentions among males and females. Strong evidence for changes in normative beliefs, however, was not obtained.

Cross-cultural research suggests that factors other than behavioural intentions may be stronger determinants of contraceptive use. An analysis of fertility survey data from Venezuela and Kenya suggests that, while intentions are significantly related to the use of contraceptives, the strength of this relationship is strongly influenced by social support, accessibility of contraceptives, conjugal communication, number of children, and desire for additional children. Moreover, the extent to which intentions influenced contraceptive use varied considerably between the two cultures (Kar and Talbot 1980).

### *Weight Control and Exercise*

A number of researchers have used the Theory of Reasoned Action to explain or predict exercise behaviour (Daltroy and Godin 1989-90; Godin 1987; Godin and Shephard 1984; Godin et al. 1986, 1987; Pender and Pender 1986; Valois et al. 1988). In a review of these studies, Godin and Shephard (1990) note that the Theory of Reasoned Action has generally been very helpful in revealing the decision-making processes underlying exercise behaviour. Approximately 30 percent of the variance in intention to exercise appears to be explained by the respondents' attitudes. Subjective norms, however, are less consistently useful.

External factors influence how intentions are transformed into behaviours (Godin and Shephard 1990). Past behaviour and the habit of exercising, for example, appear to be stable indicators of exercise behaviours (Godin et al. 1987; Valois et al. 1988).

The Theory of Reasoned Action can also explain individual preference for fat-containing foods. In a study of the high-fat food preferences of 100 female students and university employees, positive attitude, or "liking," was the main predictor of reported consumption for all the foods included in the survey (Tuorila and Pangborn 1988). Various normative belief factors, particularly those related to concern with weight, also significantly predicted consumption.

Schifter and Ajzen (1985) conducted one of the few investigations applying the Theory of Planned Behaviour to health-related issues. Per-

ceived control was a significant predictor of intention to lose weight and the amount of weight actually lost by 83 female college students over a 10-week period.

### *Smoking and Other Drug Use*

Research has shown that the smoking intentions of different groups of people can be predicted by the normative beliefs unique to each group. For example, the consequences of smoking related to physical appearance were more important than long-term health outcomes in accounting for college women's intentions to quit smoking (Chung and Fishbein 1979; Roberts 1979). Conversely, adolescents' intentions to smoke were significantly influenced by their beliefs about how friends felt about their tobacco use (Fishbein 1982).

As another example, Marín et al. (1990) interviewed 263 Hispanic and 150 non-Hispanic whites about their smoking-related attitudes and beliefs. The researchers identified a pattern of differences in normative beliefs between the two cultural groups: the family-related consequences of smoking and concerns about its unpleasant smell were stronger determinants of Hispanic attitudes toward quitting, while the effects of nicotine withdrawal contributed more to the attitudes of non-Hispanic whites. Apparently, identifying the salient normative beliefs predicting intentions to smoke, or to quit smoking, for particular groups could help in the development of anti-smoking campaigns.

Studies predicting the alcohol consumption of young people also lend support to the Theory of Reasoned Action. Schlegel et al. (1977) found that both attitudes and normative beliefs accounted for a significant proportion of the variance in the drinking intentions of male high school students. The relative importance of these two constructs varied according to social situation: normative beliefs were more influential in predicting alcohol consumption at home, a situation in which parents exert a greater degree of control. Attitudes and normative beliefs also accounted for the intentions of Australian youth to drink and drive (Sheehan et al. 1986).

### ***Strengths and Limitations of the Theory of Reasoned Action***

Relevant studies have generally supported the Theory of Reasoned Action. Applications of the theory have consistently provided strong and valid predictions of health-related behaviours in a variety of settings.

Nonetheless, some researchers have concerns. Miniard and Cohen (1981), the two authors most critical of the Theory of Reasoned Action, question whether attitudes and subjective norms can be measured independently of one another and doubt the theory's usefulness in separating personal and normative reasons for behaviours. However, the theory's creators have never stated that these variables are independent (Sheehan et al. 1986).

Carter (1990) raises some practical concerns about the theory's utility for the development of preventive interventions. Due to its complexity, a substantial commitment of resources is required to apply the Theory of

Reasoned Action to the promotion of healthy behaviours. First, a thorough and meticulous — and costly — survey of the target population is a prerequisite to designing any intervention based on the theory, since the most important issues are only identified from the attitudes and beliefs of that population. A second integral step is to determine which behavioural consequences or outcomes are most important to the priority population. At present, there is no published research suggesting appropriate shortcuts.

In addition, the use of the Theory of Reasoned Action as a conceptual basis for primary prevention and health promotion strategies is hampered by the instability of behavioural intentions over time. As Carter (1990) notes, the theory captures a snapshot of a behavioural intention, which represents only one point in time; intentions, however, are dynamic and subject to change.

Lastly, the highly circumscribed explanation of health behaviour offered by the Theory of Reasoned Action limits its application in real-world settings. Like the Health Belief Model and other individual-focussed explanations, the Theory of Reasoned Action concentrates exclusively on cognitive processes at the expense of other possible determinants of health (e.g., social and environmental factors).

## **Individual Behaviour Models: Social Learning Theory**

Social Learning Theory (Bandura 1977) views behaviour as the product of a number of personal and environmental constructs. One of the key assumptions of Social Learning Theory is the notion of reciprocal determinism, the continuous interaction between an individual, his or her behaviour, and the environment. The environment provides the social and physical settings within which a person must function, as well as incentives or disincentives (expectancies) for the performance of behaviour.

Individuals are viewed as possessing both the capability to act and the potential for control over their own behaviour. In addition, individuals can anticipate and respond to certain events or outcomes (expectations). Self-efficacy, the belief that one can perform a particular action, is another key construct employed by Social Learning Theory to account for behaviour.

According to Social Learning Theory, the acquisition of a particular behaviour is facilitated by direct or vicarious (indirect) reinforcement. Vicarious reinforcement is acquired through the process of observational learning, which occurs when an individual observes the reinforcements received by others as a result of their actions.

### ***Applications of Social Learning Theory***

#### ***Contraceptive Use and STD Prevention***

Social Learning Theory has not been as widely applied to sexual decision making as have the other models of individual behaviour reviewed in this report. The few studies that have assessed the theory as a means



of understanding contraceptive use were generally supportive of its explanatory ability.

In a retrospective survey, McKinney (1982) found that women's perceptions of personal competence at using birth control methods (self-efficacy) were associated with more effective contraceptive behaviour. Similarly, adolescent females' confidence in their ability to use contraception was positively related to contraceptive use (Levinson 1982).

In an effort to enhance self-efficacy in adolescents, Gilchrist and Schinke (1983) developed an intervention that combined factual information on reproduction and birth control with skills training and practice. The latter component included role playing sessions in which discussion of contraception was initiated, methods of contraception obtained, and unacceptable demands refused. Afterward, the adolescents demonstrated considerable improvement in their abilities to use birth control. In addition, program recipients exhibited more effective problem-solving abilities and had greater intentions to use contraception than respondents in a control group.

#### *Weight Control and Exercise*

Interventions premised on Social Learning Theory have successfully modified the eating habits of children. For example, the Home Team program, developed by Perry et al. (1988), is a correspondence course promoting healthy diets for grade 3 students. The program has been shown to significantly alter students' fat and carbohydrate consumption (ibid.).

A similar preventive effort was undertaken by Parcel et al. (1989b). The Go For Health program, delivered to children in grades 3 and 4, consisted of three main components: reduced sodium and fat content in school lunches; a physical education program designed to increase the proportion of school activities devoted to general and cardiovascular fitness; and a health education program, based on Social Learning Theory, aimed at developing students' knowledge and skills (behavioural capability), self-efficacy, and positive expectancies for healthful eating and physical activity within and outside of the school. Significant changes in the self-efficacy and behavioural expectancies of the children were accompanied by reduced salt intake and increased participation in aerobic activity.

Self-efficacy appears to be the Social Learning Theory construct most closely linked to dietary behaviours. Evidence indicates that a lack of self-efficacy is a major impediment to weight reduction.

In a study of factors associated with weight loss among middle-aged men following a behavioural treatment program, Jeffery et al. (1984) measured self-efficacy expectations at pre-treatment, post-treatment, and one-year follow-up. High pre-treatment levels of self-efficacy were significantly associated with initial and long-term (one- and two-year) weight loss.

Self-efficacy is also strongly related to current exercise and can consistently predict future exercise behaviour (Weinberg et al. 1979; Ewart et al. 1983; Sallis et al. 1989; Hovell et al. 1991). Hofstetter et al. (1990) found no direct association between self-efficacy and previous experience with exercise or sports. Factors accounting for the greatest variance in self-efficacy were environmental variables, which include home equipment and barriers; cognitive barriers, such as benefits and knowledge; and social variables, which include friends, models, and support.

These results suggest that formal recreational activities, such as school physical education classes and intramural sports, may have only a limited influence on adult physical activity. Social learning variables appear to be more important in the development of exercise self-efficacy and the subsequent performance of physical activity.

### *Smoking and Other Drug Use*

Pechacek and Danaher (1979) developed a model of smoking cessation based on social learning constructs. This model identifies outcome and efficacy expectations to help participants stop smoking and maintain that cessation. Outcome expectations influence a person's initial motivation to quit smoking, while efficacy expectations influence both initial cessation and maintenance. Studies using survey methodology support this model of smoking behaviour change (Prochaska and DiClemente 1984; Brod and Hall 1984).

Nicki et al. (1985) compared the effectiveness of self-efficacy training plus a nicotine-fading program (i.e., switching to progressively lower nicotine-content cigarettes) with self-instructional training plus nicotine fading. Individuals in the self-efficacy group were asked to choose successively more difficult situations in which to refrain from smoking. Participants in the self-instruction group were instructed to apply "self talk" to real life situations. Results indicated that self-efficacy training in combination with nicotine fading was significantly more effective than nicotine fading alone or nicotine fading paired with self-instructional training.

Several skills development programs premised on Social Learning Theory have been developed to prevent alcohol and drug abuse among young people. Among these interventions, the most widely used are the Life Skills Training Program (Botvin 1983); the Student Taught Awareness and Resistance Program (Pentz 1985); and Cognitive Behavioural Skills Training (Schinke and Gilchrist 1977). All of these programs have proven to be effective in reducing the incidence of drug use among recipients.

The Student Taught Awareness and Resistance Program (Pentz 1985) focusses on the acquisition of social assertiveness skills. Students in grades 6 to 9 who completed this training demonstrated increased levels of social competence and lower onset rates for alcohol use.

Cognitive Behavioural Skills Training (Schinke and Gilchrist 1977) focusses on smoking prevention, since this particular strategy views

tobacco as a gateway drug leading to the use of more powerful substances. Along with information about the merits and drawbacks of smoking, students learn decision-making and problem-solving skills that can be used when they encounter peer pressure to smoke. Self-instructional techniques and assertive communication skills (e.g., eye contact) are also taught. Grade 6 students who participated in the program displayed reduced intentions to smoke in the future (Schinke and Gilchrist 1984).

Life Skills Training (Botvin 1983) combines training in general life skills with instruction related to substance abuse, specifically tobacco, alcohol, and marijuana. A self-improvement component is designed to raise self-efficacy. Recipients of the program report significantly lower rates of substance use (Botvin and Eng 1982; Botvin et al. 1984).

### ***Strengths and Limitations of Social Learning Theory***

Social Learning Theory is a strong predictor of health-related behaviour. Studies have consistently found that components of the theory are strongly associated with the acquisition and performance of a number of health-related actions.

In addition, Social Learning Theory is an attractive model to apply to health education and promotion programs, as it not only illuminates the underlying dynamics of individual behaviour but also provides direction for the design of intervention strategies (Perry et al. 1990). Many intervention studies support the effectiveness of Social Learning Theory as a theoretical framework for promoting health behaviour change.

Perry et al. (1990) raise an important consideration for people who want to use Social Learning Theory in designing an effective strategy. Because Social Learning Theory emerged as a series of related components rather than as a single unified framework, one component of the theory is often examined while the rest are ignored. Placing emphasis on one component may be attractive to practitioners who prefer the simplicity of a single-variable explanation. However, failure to consider the whole theory may result in inappropriate or ineffective intervention. Therefore, Perry et al. (ibid.) recommend that designers of intervention strategies should first specify the desired behavioural change and identify the Social Learning Theory components most likely to be useful. Interventions based on the whole theory can then be designed.

### **Group Intervention Models: The PRECEDE Model**

The Predisposing, Reinforcing, and Enabling Causes of Educational Diagnosis and Evaluation (PRECEDE) framework, developed by Green et al. (1980), is another approach to planning and implementing health education programs. Uniquely, this framework, depicted in Figure 2, focusses the health educator's initial attention on desired results, thereby forcing the educator to begin with the planning process in mind.

There are seven main phases in the PRECEDE framework. Phase 1 is an assessment of the general problems faced by the priority population.



The objectives of phase 2 are to determine the health problems that appear to be contributing to the problems noted in phase 1, and to select the problem most deserving of resources. Phase 3 consists of identifying health-related behaviours and non-behavioural factors that appear to be linked to the health problem selected in phase 2. In phase 4, the factors that seem to have a direct impact on the behaviours identified in the previous phase are classified into one of three main categories: predisposing factors, the personal attitudes or beliefs that help or hinder personal motivation for change; enabling factors, barriers to the change, skills, or knowledge required for a desired behaviour to occur; and reinforcing factors, feedback from others that may either help or hinder the maintenance of a behaviour over time. The educator decides which of these factors will be the focus of the intervention in phase 5. Phase 6 is the actual development and implementation of the program. Evaluation, the final phase of the PRECEDE Model, occurs throughout the entire process.

### ***Applications of the PRECEDE Model***

The PRECEDE Model has guided the development of numerous health education and health promotion programs. At present, however, a few studies have used the model to study or modify infertility-related risk factors. Results support the PRECEDE approach to planning and delivering preventive interventions.

Mullen et al. (1987) compared the predictive abilities of the PRECEDE Model with those of the Health Belief Model and the Theory of Reasoned Action in an evaluation of a U.S. health promotion campaign. Self-reports of smoking, exercise, and the consumption of sweet and fried foods were collected from a group of 326 adults. With the exception of attempts to quit smoking, a behaviour more accurately predicted by the Theory of Reasoned Action, the PRECEDE Model was more useful than the other theoretical frameworks. However, the PRECEDE Model required far more items to assess its components.

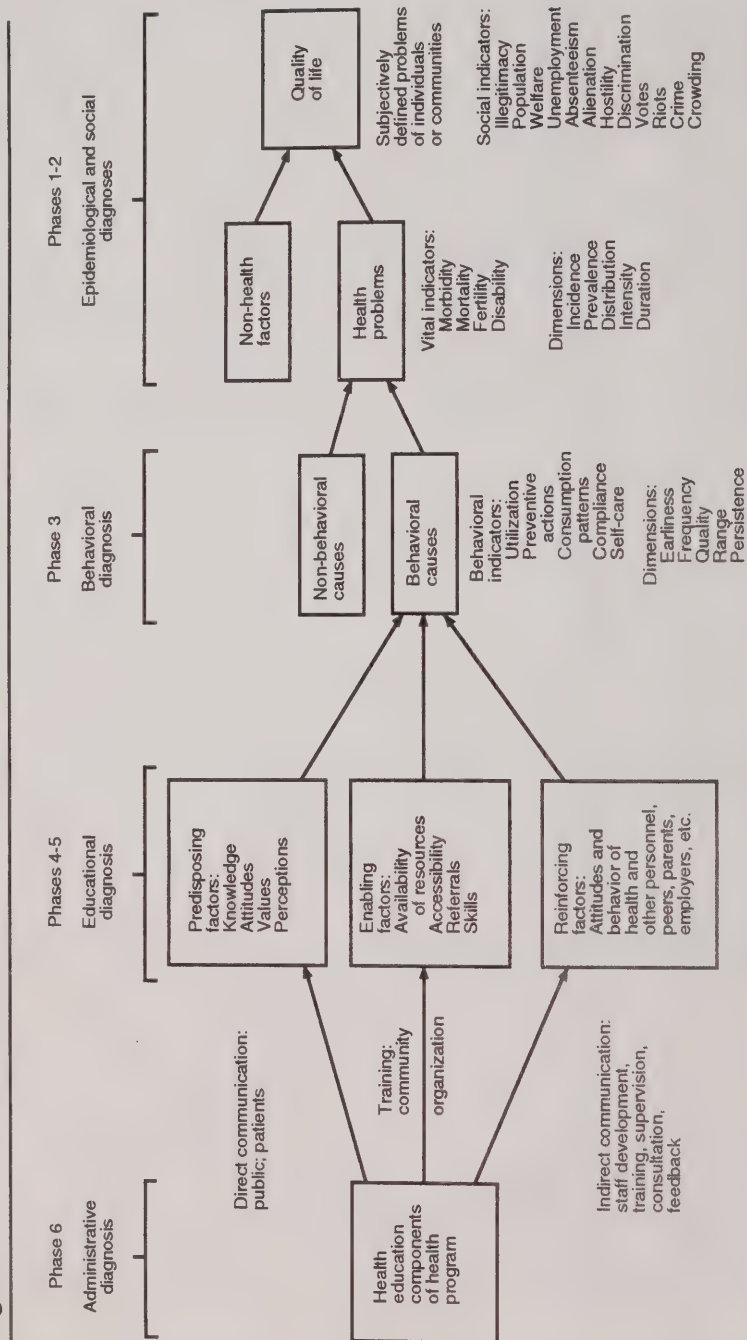
The PRECEDE Model served as the theoretical basis for a program encouraging low-income, hypertensive patients to comply with their prescribed dietary and blood pressure control regimens (Morisky et al. 1983).

A five-year evaluation of the program revealed a continuing positive effect on the participants' appointment keeping, weight control, and blood pressure control. The mortality rate of program recipients was 57.3 percent less than that of a control group ( $p < .05$ ), while the hypertension mortality rate was 53.2 percent less ( $p < .01$ ).

Windsor et al. (1985) used the PRECEDE Model to develop a self-help guide to assist pregnant women in overcoming their smoking habit in seven days. Evaluation indicates that the guide is an effective aid for smoking cessation, facilitating behavioural change in about one in three women.



Figure 2. The PRECEDE Model



Source: L. W. Green et al., *Health Education Planning: A Diagnostic Approach* (Mountain View, California: Mayfield, 1980).

### ***Strengths and Limitations of the PRECEDE Model***

Based on the available evidence, preventive interventions premised on the PRECEDE framework appear to be highly effective in encouraging behaviour and promoting environmental changes conducive to health. In addition, the PRECEDE Model attempts to facilitate the maintenance of behavioural change over time, a consideration overlooked by other theoretical frameworks.

Health education experts should be aware that the proper application of the model necessitates a significant commitment of time and both human and financial resources. Not only is ongoing evaluation required, but a comprehensive needs assessment is also needed, including a complete appraisal of the lifestyle and social conditions under which the target population lives and epidemiological research documenting the targeted health problem. Accordingly, adoption of the PRECEDE Model as a basis for program planning and delivery may be beyond the means of many organizations.

### **Group Intervention Models: Diffusion of Innovations Theory**

An innovation is an idea or practice that is perceived as new by an individual. Diffusion is the process by which an innovation is communicated over time among the members of a social system. Diffusion of Innovations Theory, developed by Rogers (1962, 1983), is an attempt to explain this process and to determine the most effective way of disseminating potential solutions to real problems, including poor health.

Research has consistently shown that individuals are more likely to adopt innovations that are compatible with their own value system; flexible enough to be used in a wide variety of settings; reversible if individuals wish to revert to previous practices; relatively advantageous when compared with alternatives; simple enough for individuals to understand; cost-efficient, so the perceived benefits outweigh the perceived costs; and low-risk (Kolbe and Iverson 1981).

The innovation development process progresses over six stages: recognition of a problem or need; basic and applied research; developing the idea into a form expected to meet the needs of potential adopters; commercialization, involving production, marketing, and dissemination of the innovation; diffusion and adoption; and consequences.

Diffusion of Innovations Theory classifies individuals according to the length of time they take to adopt new ideas and customs. The six categories conventionally used are innovators, early adopters, early majority, late majority, late adopters, and laggards (Rogers 1983). Early adopters usually have the greatest social influence in a community, and are therefore in a key position to encourage wider adoption.

## ***Applications of Diffusion of Innovations Theory***

### ***Contraceptive Use and STD Prevention***

The diffusion of contraceptive use was extensively studied through the KAP (knowledge, attitudes, and practice) projects, a series of surveys conducted in developing nations during the 1960s and early 1970s. One of the earliest and most successful KAP initiatives took place in the Taiwanese city of Taichung (Berelson and Freedman 1964). Four different communication interventions derived from Diffusion of Innovations principles were implemented in the Taichung study: neighbourhood meetings about family planning; neighbourhood meetings plus information about family planning mailed to likely adopters; neighbourhood meetings plus personal visits to the wives in families of likely adopters; and neighbourhood meetings plus personal visits to both husbands and wives.

The Taichung project proved to be a highly effective means of encouraging contraceptive use. Forty percent of the female program recipients adopted some form of family planning, and pregnancy rates immediately decreased by 20 percent. Over three-quarters of the women deciding to use contraception chose IUDs, the main type of birth control promoted by the project (Berelson and Freedman 1964).

Subsequent KAP studies did not yield results comparable to those achieved by the Taichung project. The failure of these and other initiatives to alter contraceptive behaviour significantly has led Rogers (1983) to conclude that birth control methods are one of the most difficult types of innovations to diffuse: the inherent characteristics of contraceptive use, such as lack of compatibility with existing value systems, are hindrances.

### ***Weight Control and Exercise***

As was previously noted, early adopters of innovations usually have a higher degree of social status in the community than subsequent adopters. Diffusion of Innovations Theory contends that encouraging local opinion leaders to embrace a new practice is an effective means of fostering acceptance of the innovation throughout the community. Several community-based cardiovascular disease prevention projects, partly aimed at promoting a healthy diet and exercise regimen, pursued this strategy.

Puska et al. (1985) systematically identified informal opinion leaders in North Karelia, Finland, the site of a highly successful and influential cardiovascular disease prevention project. These individuals underwent training that increased their awareness of risk factors related to heart disease and enabled them to assist in the planning and delivery of the project's interventions (e.g., public awareness activities).

The North Karelia project was highly effective, yielding significant reductions in serum cholesterol level, blood pressure, and cardiovascular disease mortality rate ( $p < .001$ ). It should be noted, however, that the project was premised on a number of theoretical frameworks, so its success cannot be attributed solely to Diffusion of Innovations principles.



Interventions used in the Minnesota Heart Health Program (Mittelmark et al. 1986) and the Welsh Heart Program (Nutbeam and Catford 1987) were also based, in part, on Diffusion of Innovations Theory. Key community leaders were asked to serve on an advisory board that coordinated the Minnesota Heart Health Program activities. The Welsh Heart Program directorate established working relationships with local politicians and decision makers in the hope that these individuals would facilitate change through personal example. The results of these initiatives are not yet available.

### *Smoking and Other Drug Use*

Diffusion of Innovations Theory has been used to account for trends in the adoption of tobacco use and to encourage the adoption of smoking prevention programs. Results of these applications have supported the basic principles of the model.

To encourage school districts to adopt an effective prevention program, Parcel et al. (1989a) designed an intervention based on Diffusion of Innovations Theory and Social Learning Theory. Modelling techniques communicated the relative advantages, compatibility, and flexibility of the program. Skills training prepared teachers for the implementation of the program, and incentives were provided to encourage program adoption and maintenance. Nearly 60 percent of the school districts in the targeted regions adopted the program as a result of the intervention (Parcel et al. 1990).

Ferrence (1989) analyzed cross-sectional survey data to determine the value of Diffusion of Innovations Theory in accounting for demographic trends in tobacco use. In most instances, variations in smoking patterns by sex, country, region, occupation, and education were predictable by the theory. Both adoption and cessation of smoking occurred earlier among males, U.S. smokers, those born or living in regions predicted to have earlier adoption and cessation, and those with high status occupations or a higher level of education. Sex was the strongest determinant of smoking during the adoption phase, while social status had the greatest influence on cessation.

The negative relationship between smoking and socioeconomic status, a finding consistently obtained in surveys, is in accordance with the tenets of Diffusion of Innovations Theory. Rogers (1983) suggests the following strategies for reducing the prevalence of tobacco use among economically disadvantaged groups: messages appropriate to that audience should be provided to enable them to "catch up"; messages should be developed specifically for this audience according to their education, beliefs, and values; the outlets of communication most widely used by groups of low socioeconomic status should be used to convey this information; and people promoting cessation may need to be drawn from groups of low socioeconomic status if they are to have the credibility needed to facilitate changes in behaviour.



### ***Strengths and Limitations of Diffusion of Innovations Theory***

One of the main strengths of Diffusion of Innovations Theory is its ability to predict the rate of adoption of a new practice. This explanatory power is valuable for setting quantified objectives for health promotion programs, as well as for evaluating program results against a theoretical standard of acceptability (Green et al. 1991).

Moreover, the theory allows for specification of the characteristics typically found in the segments of the population most likely to adopt the innovation. The specification enables the health educator to anticipate the strategies and resources most likely to be required during successive phases of the program (Green et al. 1991).

Although Diffusion of Innovations Theory has made a substantial contribution to understanding how health-related behaviours are adopted over time, it has been challenged (Basch et al. 1986-87; Orlandi et al. 1990). First, assuming that the innovation is readily transferable directs attention toward the potential adopter and away from the possibility of refining the innovation to improve the fit between the innovation and the adopter. The second limitation of Diffusion of Innovations Theory is that it fails to provide an adequate means of evaluating the impact of external variables on the adoption of innovations; the diffusion process, as a rule, is viewed as static rather than dynamic. Third, the theory views the adoption of a behaviour, rather than a behaviour's maintenance over time, as the main criterion of success.

Lastly, many critics of Diffusion of Innovations Theory are uncomfortable with its implicitly elitist assumption that health-promoting behaviours will naturally "trickle down" to economically disadvantaged groups over time. Green et al. (1991) respond to this issue by noting that the theory does not state that one must wait for a new practice to reach the most marginalized segments of the population, assuming that these groups will be late adopters regardless of any measures taken to reach them. In fact, the rate of adoption in any portion of the population can be accelerated through more intensive communication and outreach.

### **Group Intervention Models: Social Marketing**

Social Marketing is the application of techniques used by commercial advertising in order to encourage people to adopt health-promoting practices. The underlying assumption of this approach is that it will be able to modify behaviour through its capacity to influence the attitudes or beliefs of a particular target population (Kotler and Zaltman 1971).

Social Marketing campaigns have adopted the "4 P's" strategy, which focusses on four main factors: product, the desired change in attitudes or behaviour; price, the time involved in implementing the campaign or the costs of behaviour change for individuals; place, the positioning of the campaign message; and promotion, the channels of communication utilized by the campaign. Thus, the elements of a successful Social Marketing

campaign are the right product, at the right price, in the right place, backed by the right promotion (Mintz 1988-89).

## ***Applications of Social Marketing***

### *Contraceptive Use and STD Prevention*

A number of Social Marketing campaigns have encouraged contraceptive use in developing nations. Most of these ventures were successful, although several failed due to inadequate resources or lack of political support (Altman and Piotrow 1980). It should be noted, however, that these programs did not consist solely of media appeals: contraceptives were provided to consumers at subsidized prices or were distributed free of charge.

Social Marketing campaigns encouraging contraceptive use and safer sex practices in developed nations have been less successful. Evaluations of these initiatives have found them to be effective in increasing public awareness and knowledge (Kapila and Pye 1992), but there is little evidence that Social Marketing campaigns have led to changes in high-risk sexual behaviours.

Moreover, there is some evidence that poorly conceived Social Marketing strategies aimed at preventing STDs may inadvertently raise unnecessary anxieties or fears in the targeted audience (Nutbeam and Blakey 1990). Evaluations of campaigns relying on fear-inducing messages, such as Australia's "grim reaper" and the United Kingdom's "Don't die of ignorance" appeal, suggest that these endeavours had little or no effect on sexual behaviour and may well have induced unnecessary anxiety among the general public (Hastings and Scott 1987; Wober 1987; Nutbeam et al. 1989; Rigby et al. 1989).

### *Weight Control and Exercise*

Social Marketing techniques have been successfully used to promote healthy diet and exercise habits. There is some evidence that the efficacy of such campaigns is enhanced by more interpersonal methods of communication that provide individuals with the skills for sustained behaviour change.

The effects of a mass media campaign supplemented by personalized instruction were assessed in the Stanford 3 Community study, an investigation conducted in three northern California towns (Farquhar et al. 1977). Over two years, two of the communities were exposed to extensive Social Marketing campaigns promoting healthy diets, weight control, exercise, and smoking cessation. Intensive, face-to-face instruction was provided to high-risk individuals in one of the communities receiving the media campaign. The third community was a control. Residents of each community were assessed for cardiovascular disease risk factors before the campaign and one, two, and three years afterward.

In the community receiving both mass media and intensive instruction, the initial decrease in risk behaviours was greatest. This

decrease was matched by the media-only community for some risk factors, but not for smoking or relative weight. Risk in the control community increased over the survey period (Farquhar et al. 1977; Maccoby et al. 1977; Farquhar 1980).

Media messages and more personalized educational methods were successfully combined in the (U.S.) National High Blood Pressure Education Program, a cooperative effort involving federal agencies, state health departments, and private organizations (Ward 1984). Since its inception in 1972, the program has applied marketing principles to the strategic development, pretesting, production, and assessment of its educational messages. Initial communications were aimed at increasing public awareness of the health risks of high blood pressure. Over time, the focus of the messages shifted to preventive measures such as weight control and exercise.

Evaluation data indicate that the program has made substantial progress in raising public awareness of hypertension and controlling its effects. The percentage of the U.S. adult population aware of the relationship between high blood pressure and heart disease increased by over 60 percent between 1983 and 1985, while the percentage of the population aware of the link between high blood pressure and stroke increased by 48 percent over the same time period (U.S. National Center for Health Statistics 1985). The percentage of hypertension patients achieving long-term control over their condition increased by approximately 8 percent between 1971 and 1975, while the age-adjusted mortality rate for strokes fell by 30 percent between 1972 and 1978 (Levy and Ward 1979; Ward 1984).

### *Smoking and Other Drug Use*

Social Marketing campaigns encouraging smoking cessation have been implemented with varying degrees of success. In a review of 40 such initiatives, Flay (1987) found that media messages about the effects of smoking or motivating individuals to quit generally yielded positive changes in knowledge, awareness, and attitudes. In addition to affecting knowledge and attitudes, extensive national campaigns appeared to produce meaningful behavioural change. However, the delivery of these nation-wide media appeals coincided with a variety of anti-smoking measures. Media campaigns designed to promote a specific smoking-related action, such as requesting a smoking cessation kit, yielded mixed outcomes, depending on the type of promotion involved.

The results of the Finnish TV-2 series, an anti-smoking media campaign based on Social Learning Theory, underscore the need to supplement Social Marketing campaigns with interpersonal instruction. Several hundred volunteers in the North Karelia region of Finland were trained to provide social reinforcement as a supplement to the TV-2 campaign. Significantly higher rates of smoking cessation were observed among the population in this area (Green and McAlister 1984).



Social Marketing techniques have been less successful in reducing the prevalence of alcohol and other drug use. Barber and Grichting (1990) reviewed media-based substance abuse prevention campaigns conducted in Canada, Australia, the United States, and Great Britain. The impact of these interventions was very limited; at best, they seem to have resulted in increased knowledge and short-term changes in attitude.

### ***Strengths and Limitations of Social Marketing***

Social Marketing's main strength is its ability to provide easy access to large numbers of a target group. In addition, the application of marketing techniques fosters a greater understanding of the people whom the health educator wishes to reach (Sarner 1984; Mintz 1988-89). Although Social Marketing's ability to change behaviour has proven to be limited, there is some evidence that media messages may trigger dramatic changes in behaviour when individuals are already motivated to change (Tones et al. 1990).

While effective, Social Marketing does have some significant limitations. One of the primary drawbacks to Social Marketing is its low impact. Tones et al. (1990) estimate that the most effective Social Marketing campaigns increase the probability of achieving desired program objectives by only 15 percent. Media messages have minimal impact on individuals who are highly resistant to change, and these messages fail to foster change in highly motivated individuals who lack the necessary economic or social resources to alter their behaviour.

The high costs of developing, delivering, and evaluating media campaigns prohibit many organizations from adopting Social Marketing techniques. Moreover, the resources available cannot begin to compete with the multi-million dollar budgets of commercial media appeals, many of which contradict the messages delivered through Social Marketing (Wallack 1983).

Social Marketing messages cannot adequately convey complex messages or create understanding of the often complicated issues related to health. In addition, Social Marketing techniques are incapable of teaching complex health-related skills, such as breast self-examination or the ability to deal assertively with interpersonal pressures (Tones et al. 1990).

Lastly, there is some concern that many Social Marketing campaigns constitute a form of victim blaming, as they implicitly hold individuals responsible for their own health while ignoring the social or environmental factors that may hinder healthy behaviours (Crawford 1977). In response to this contention, proponents of Social Marketing maintain that marketing techniques are value-neutral tools; those who use these tools are responsible for the content of the messages derived from them.

In spite of its shortcomings, Social Marketing has gained widespread acceptance. Health educators wishing to mount Social Marketing campaigns should be aware of the considerable body of evidence indicating



that the strategy has only limited power to alter behaviour and should therefore be combined with other interventions to enhance its effectiveness.

### Group Intervention Models: Community Organization Methods

Community organization is the process by which community groups are assisted in identifying commonly shared problems or goals, mobilizing resources, and developing and implementing strategies for reaching their goals (Minkler 1990). Implicit in this definition is the concept of empowerment, an enabling process through which individuals or communities take control over their environment (Rappaport 1984). Community organization is often referred to as community mobilization or community development.

The type of community guides the health educator's approach to community mobilization. While traditionally defined in geographic terms, communities may also be based on shared interests such as ethnicity, socioeconomic status, sexual orientation, or occupation (Fellin 1987).

Rothman (1970) identified three main approaches to community organization. Locality development is a consensus approach, seeking maximum community participation and relying on the community's initiative as much as possible. Social planning, by contrast, addresses community problems through rational, controlled change initiated by expert planners with varying degrees of community support. Social action, a more confrontational, politicized approach, seeks to redistribute power and resources to marginalized segments of the community. Rothman notes that these models are not mutually exclusive, but most community organization efforts nevertheless exhibit salient features that place them in one of the three categories.

Perhaps the most important contributions to the field of community organization are the *contientizacion* or popular education methods developed by the Brazilian educator Paulo Freire (1973). Freire argues that education, including the understanding gained through participation in community efforts, is not neutral: it takes place within the context of existing social and political realities. Traditional didactic education methods have been criticized by Freire for socializing people to accept a limited role in society.

As an alternative, Freire proposes a dialogue approach, where everyone participates as equals or co-learners. This method, in which the teacher assumes a facilitative role, is implemented in four stages: listening to the issues raised by the group; talking together about the issues raised; developing codes, that is, concrete physical representations of the identified issue (e.g., a drawing); and acting, or making the positive changes envisioned by the participants. Popular education has been adopted in a number of health-related community organization projects (Minkler and Cox 1980; Auerbach and Wallerstein 1987; Wallerstein and Bernstein 1988).

## ***Applications of Community Organization Methods***

### ***Contraceptive Use and STD Prevention***

Community-based approaches to family planning services have been successfully implemented in a number of developing countries. Kols et al. (1982) note that these endeavours share four essential features: supplies (i.e., contraceptives) are delivered by community members who are not health professionals; health services are provided outside of traditional clinics; community health workers operate autonomously with no direct, daily supervision; and many diagnostic and record-keeping procedures are omitted, as they are impractical in a community setting. These programs increase community access to family planning services, since they are provided free or for minimal charge by people known in the community. Moreover, these services are unhampered by bureaucratic obstacles such as long waiting periods, lengthy forms, and limited hours of operation.

Kaseje et al. (1987) assessed the impact of a community-based family planning program in Saradidi, Kenya. Family planning services in each village were delivered by volunteers chosen and supported by the local residents. The use of birth control methods by women in the communities provided with this service increased by 17 percent within three years of its initiation.

Methods of community organization have also been applied to prevent the spread of STDs. In recent years, most of these efforts have focussed on reducing the incidence of the human immunodeficiency virus (HIV). In the spring of 1982, for example, the gay community in New York City formed the Gay Men's Health Crisis (GMHC) in response to the increasing prevalence of AIDS, which was then relatively unknown (Shilts 1987). Later that year, the GMHC established the first AIDS information hotline. In 1983, gay community organizations in San Francisco launched a major AIDS prevention campaign (Shaw 1988). These early efforts served as models for the hundreds of similar groups that have since developed in the United States, Canada, Europe, and Australia.

In a summary of the community-based responses to HIV in Canada, Clausson (1989) notes that most community AIDS groups are volunteer, non-profit organizations with a mandate to provide four basic services: education and information, prevention, support, and advocacy. Nearly all community groups operate telephone hotlines to answer basic questions about AIDS and produce and distribute posters, brochures, videos, and other educational material. Prevention activities include the delivery of safer sex workshops, as well as the distribution of condoms and information on preventive measures. Virtually all community organizations offer support groups and counselling to HIV-positive individuals and the families, friends, and partners of people living with AIDS. Lastly, community-based AIDS prevention groups advocate on behalf of people with AIDS who suffer from discrimination or who have problems gaining access to social or health care services.

Some AIDS prevention groups have adopted a more confrontational approach to community mobilization. The best known organization employing social action strategies is Act Up in New York City, which relies on "die ins," demonstrations, and acts of civil disobedience to raise public awareness of AIDS-related issues and to lobby for needed reforms.

Unfortunately, there is a dearth of information on the effectiveness of the behavioural change strategies implemented by community-based AIDS groups (Coates 1990). The lack of evaluation research may partly be due to a lack of time and expertise on the part of the service providers. Most evaluations of community-based AIDS prevention programs use outreach measures (i.e., number of people served) as the main criterion of success (e.g., Bruhn 1990). Positive changes in behaviour have been observed in certain high-risk groups since education has become available (Winkelstein et al. 1987; Becker and Joseph 1988; Coates 1990; Ekstrand and Coates 1990). However, the extent to which these changes are attributable to community-based strategies has not been ascertained.

### *Weight Control and Exercise*

The principles of community organization have contributed to the theoretical framework of a number of cardiovascular disease prevention programs promoting healthy eating and exercise habits. The Minnesota, Pawtucket, and Stanford 5-City Heart Health promotion programs used community organization as a guide for developing channels of citizen participation (Shea and Basch 1990). The approach to community organization taken by the North Karelia project relied on self-development at the local level as well as the use of outside people to promote restructuring (Puska et al. 1985).

All of these projects relied heavily on community resources to support their interventions. Through the efforts of the North Karelia and Pawtucket projects, local residents were recruited and trained to provide a number of community-based services, such as weigh-in clinics and risk-factor screening services (Puska et al. 1985; Lefebvre et al. 1987; Roncarati et al. 1989). In addition to training volunteers, the Minnesota Heart Health project sought the advice of community members (Mittelmark et al. 1986).

At present, evaluation data are available for two of these initiatives. Results of the North Karelia project were summarized in a previous section of this report. The Stanford 5-City program resulted in significant reductions in smoking, blood pressure, cholesterol levels, and cardiovascular disease mortality (Farquhar et al. 1990). Since these projects used a variety of interventions, including extensive Social Marketing, the extent to which community organization strategies contributed to the results cannot be determined.



### *Smoking and Other Drug Use*

A number of community-based projects are trying to prevent the use or abuse of tobacco, alcohol, or other drugs. The nature and degree of community involvement in these endeavours varies considerably.

The Texas A Su Salud Project, a smoking cessation strategy combining community mobilization with the principles of Social Learning Theory, was implemented in a community of low-income Mexican-Americans (Amezcua et al. 1990). The rationale underlying the A Su Salud Project is that preventive interventions should create a supportive environment and enhance an individual's ability to make behavioural changes.

Amezcua et al. (1990) organized the community around three main strategies. The first component used role models who demonstrated ways to stop smoking. Local residents volunteered to model practices at which they were proficient, and their demonstrations were disseminated through newspapers, radio, and television. The second component involved recruiting several hundred volunteers to establish a community network, which was used to raise awareness about the role models and their behavioural change strategies. The third component provided individual and family counselling for managing stressful life events that impeded healthy behaviour change.

Preliminary assessments of the project reveal that media modelling combined with reinforcement and support from lay volunteers was more effective than media modelling alone in fostering and maintaining smoking cessation. In addition, there is some evidence that the counselling and referral services were effective in increasing cessation among women but not among men.

Pentz et al. (1989) used community mobilization to delay the onset of cigarette, alcohol, and marijuana use by young adolescents. A community coordinating team of school and community leaders planned and coordinated the intervention. The program consisted of 10 educational sessions supplemented by homework assignments and mass media coverage. In a one-year follow-up survey, students participating in the program reported significantly lower use of tobacco, marijuana, and tobacco than their control group counterparts.

Popular education principles are incorporated into an alcohol education program for Native American adolescents in New Mexico (Wallerstein and Bernstein 1988). Through the Alcohol and Substance Abuse Prevention program, administered by the University of New Mexico, small groups of high-risk Native American youth visit the university hospital emergency centre and the county detention centre where they interview patients and residents with substance abuse problems. University students and faculty are trained to act as group facilitators. The small groups meet regularly to discuss their experience and consider factors encouraging alcohol consumption. The popular education process



of listening, talking together, making codes, and acting (Freire 1973) is incorporated into the program components.

Program participants at selected schools were given a pretest and post-test measure. Results at one school indicate a significant increase in the participants' perceptions of alcohol as a dangerous substance (Wallerstein and Bernstein 1988).

### ***Strengths and Limitations of Community Organization Methods***

Community organization is one of the most popular and widely used health promotion strategies. It is probably the most effective means of providing interventions that match the prevention needs of the target population, because representatives of that population have direct input into program planning and delivery. Moreover, community development is the most democratic form of program implementation, providing the recipients with direct channels for participation and holding public institutions accountable for their actions (Koneya 1978).

One of the primary challenges faced by community organizers is the difficulty of evaluating their efforts. The random assignment of respondents to experimental or control conditions, a cardinal tenet of quantitative assessment, is seldom feasible in community-based research (Goodstadt 1990). Samples are usually drawn from whichever community members or groups are willing to participate. The objective appraisal of community mobilization is further compromised by the inevitable loss of respondents over time. In addition, political considerations (e.g., omitting sensitive items from a questionnaire) can also affect the evaluation design and the dissemination of results. As a result of these impediments, many community organizers prefer qualitative methods of assessment, focussing on the perceptions of the community participants.

Most community mobilization efforts purport to empower the target group in one form or another, but all too often this objective is not met. In many instances, community organizers erroneously assume that community members possess the requisite knowledge, skills, and power for meaningful participation. As a result, community organization initiatives may produce a disempowering effect: community members may feel overwhelmed and incapable of addressing their shared concerns.

To facilitate a meaningful level of community participation, Piette (1990) suggests that training provided to community members should encompass the following: understanding of how experts approach problems; development of self-reliance; and the introduction of leadership, teamwork, and negotiating skills. In addition, community members should be provided with the knowledge and skills necessary to maintain the developed programs and services over time.

Community mobilization strategies have been criticized for various reasons, including their tendency to overlook the most marginalized segments of a community, their lack of meaningful outlets for citizen participation, and their inclination toward professional domination (Koneya

1978; Carniol 1983). However, these criticisms pertain to the implementation of community organization methods rather than to the methods themselves. Participatory approaches to community organization can elicit high levels of meaningful citizen involvement, build leadership skills, and increase community competence. Any method of community organization capable of achieving these objectives is a valuable health promotion strategy.

## **Prevention Target Models**

### ***The AODAM Model***

The Alcohol and Other Drug Abuse and Misuse (AODAM) Model, illustrated in Figure 3, is designed to help planners identify the environmental factors that strongly influence the rates of substance abuse in their communities (Shain et al. 1991). Although the model emphasizes environmental influences, it does not ignore the importance of individual determinants. The model underscores the way in which personal resources, such as self-esteem and sense of competence, are influenced by the environments in which people live.

The primary environmental influences identified by the model are community, family, workplace, health and social services, school, and society at large. It is difficult to ascertain which influence precedes which, although individuals tend to progress from family to school to workplace as they mature. These influences, which constantly interact with one another, affect the likelihood that health problems will develop by reinforcing or eroding the individual's personal response.

Personal resources include people's overall physical, emotional, social, and spiritual health as well as their ability to earn income (or otherwise be self-supporting), manage their lives, gather and process information, be assertive, communicate, give and receive affection, fulfil parental or caregiving roles, and cope with stress. Although health is a personal resource, it affects, and is affected by, all of the other personal resources.

The relationship between environmental influences and personal resources is reciprocal. Personal resources are influenced by the environment, and provide a means of coping with the environment.

## **Sociostructural Theories of Health Behaviour**

The sociostructural theory of health behaviour, depicted in Figure 4, has a "meso-micro" focus, as it notes the role played by social factors in health behaviour without overlooking the influence of individual actions. According to Noack's theory, health-related actions are determined by two factors: the social system and individual/collective actions.

Health-related behaviour is the product of three primary factors influenced by the social system and individual or collective action. Health-related rules are specific patterns of preventive actions, practices, and coping behaviours. These rules are set out by the social system as prescriptions or schemes governing patterns of health-related behaviours. Health resources are also determined by the social system and are used as knowledge and experience at the individual or collective level. Lastly, health motivation refers to the health-related desires or requirements of individuals or to the health-related objectives shared by collectives.

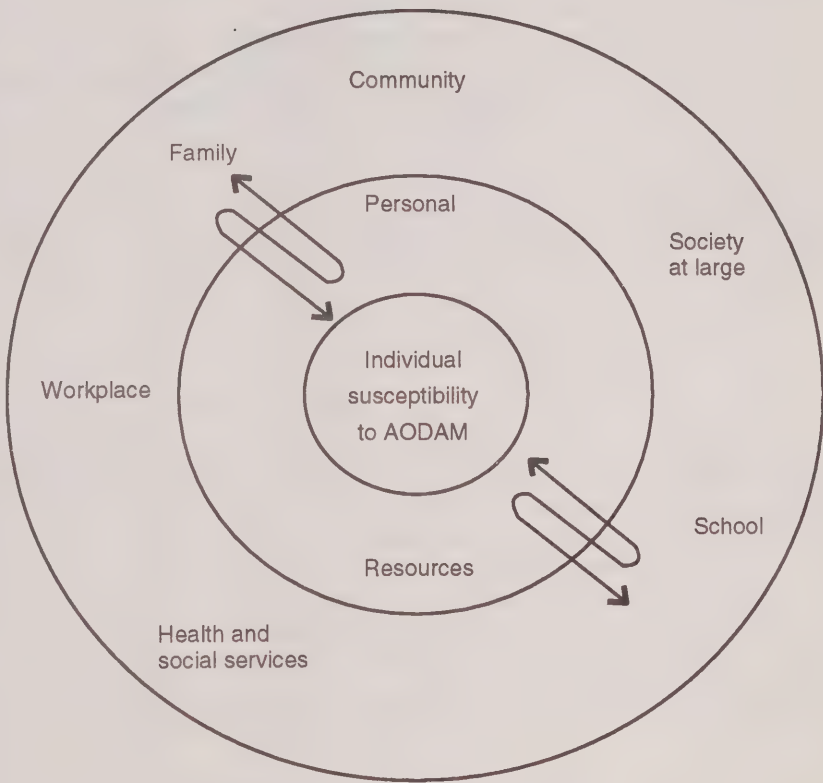
Noack's sociostructural theory can be applied to account for the maintenance of behaviour over time and the evolution of behavioural changes in society. At the individual or collective level, these processes are influenced by the degree of autonomy individuals and collectives (e.g., families) possess and the extent to which they are dependent on the social system. The social system relies on communication, use of power, and sanctioning to control health behaviours.

McKinlay (1981) developed a sociostructural model of health behaviour with a more macro or societal focus. Unlike Noack, McKinlay sees no role played by the individual; the social system's influence is all-encompassing. The other distinguishing feature of McKinlay's model, illustrated in Figure 5, is its exclusive focus on negative health behaviours or health risks.

According to McKinlay, the unhealthy behaviours of individuals are directly attributable to the activities of the manufacturers of illness. This term refers to any person, group, or organization producing goods or services (e.g., tobacco products) that have a deleterious impact on the health status of a population. In turn, the resulting risk behaviours invariably lead to observable morbidity and mortality.

At each stage of the model, McKinlay identifies the type of intervention necessary to improve the health of individuals affected by the manufacturers of illness. Intervention with a political-economic focus, such as the implementation of various forms of healthy public policy, is needed to curb the activities of those responsible for producing illness-enhancing products. Intervention with a preventive focus (e.g., public education) is required to dissuade individuals from health-damaging behaviours. Lastly, intervention with a curative focus, otherwise known as secondary prevention or treatment, should be used to lower the morbidity and mortality rates of those currently behaving in ways that are harmful to their health.

**Figure 3. The AODAM Model**

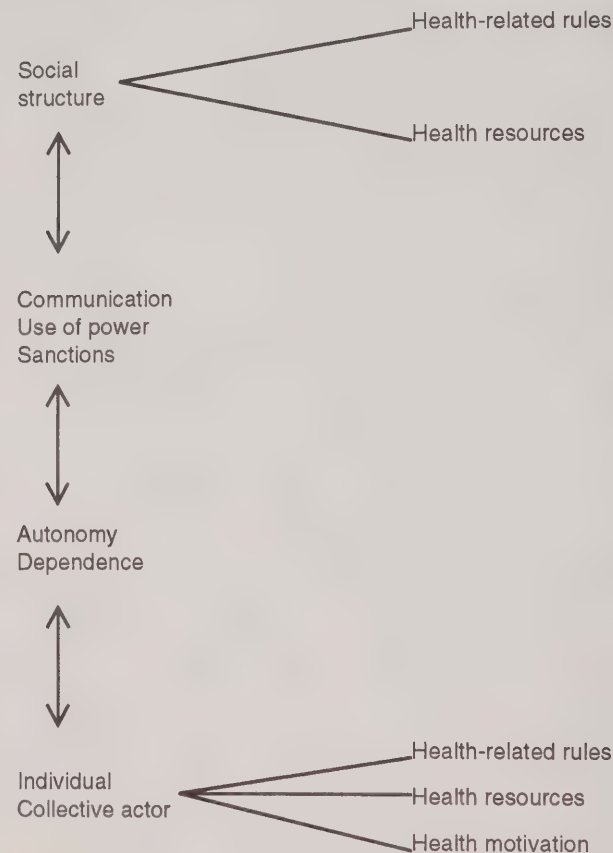


**Note:** The wavy arrows suggest reciprocal relationships between the environment in the outer circle and personal resources.

**Source:** M. Shain et al., *Prevention Through Health Promotion: Environmental Strategies for Reducing the Risk of Drug Abuse* (Toronto: Addiction Research Foundation, 1991).



**Figure 4. Noack's Theory of Health Behaviour**



**Source:** H. Noack, "The Role of Socio-Structural Factors in Health Behaviour," in *Health Behaviour Research and Health Promotion*, ed. R. Anderson et al. (Oxford: Oxford University Press, 1988).

**Figure 5. McKinlay's Theory of Health Behaviour**

<b>Stages</b>	Activities of the manufacturers of illness	→	Various at- risk behaviours	→	Observable morbidity and mortality
<b>Interventions</b>	Intervention with a political- economic focus		Intervention with a preventive focus		Intervention with a curative focus

**Source:** J.B. McKinlay, "A Case for Refocussing Upstream: The Political Economy of Illness," in *The Sociology of Health and Illness: Critical Perspectives*, ed. P. Conrad and R. Kern (New York: St. Martin's Press, 1981).

## The Epidemiological Triangle

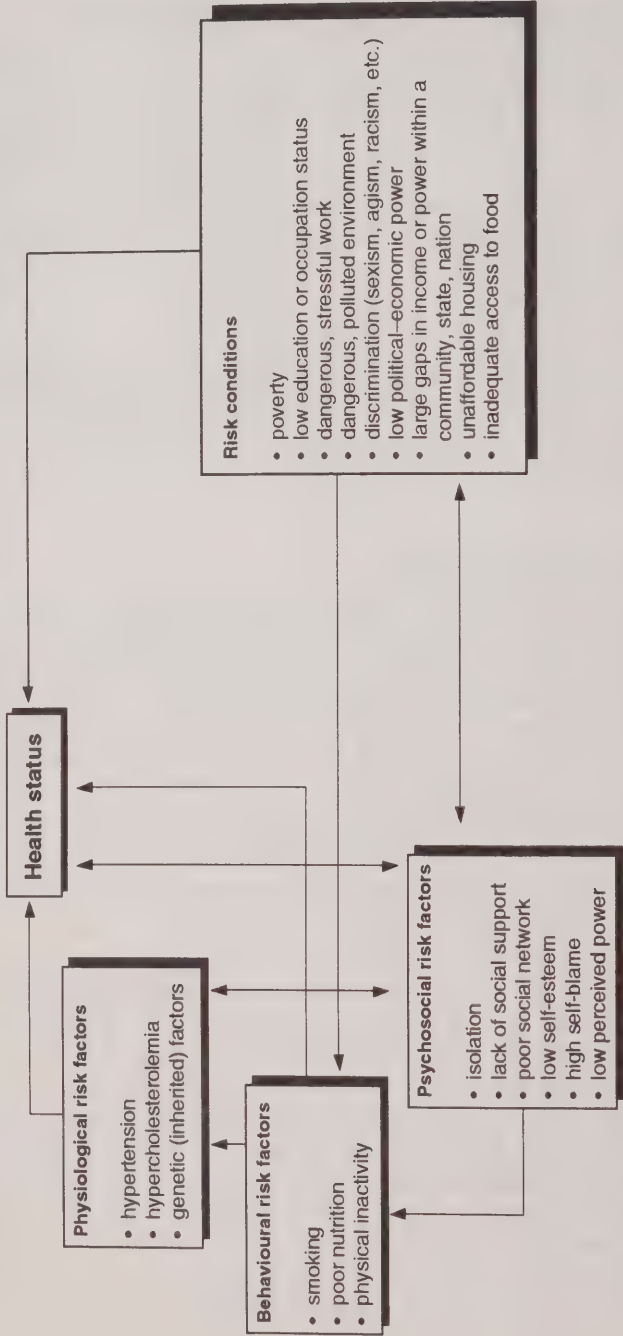
The traditional epidemiological model of disease, also known as the Epidemiological Triangle, consists of three main components: agent, host, and environment (Dever 1980). Agents of disease include infectious organisms, physical sources, allergens, chemical sources, and nutritional deficiencies. Host factors are intrinsic elements influencing an individual's susceptibility to a particular agent. Environmental factors are extrinsic entities that influence an individual's exposure to a particular agent.

Factors in each of the categories interact to produce disease. Changes in any one of the three components will alter an existing equilibrium to increase or decrease the frequency of disease.

## The Socioenvironmental Approach to Health

The Socioenvironmental model was developed by the City of Toronto Department of Public Health (1991). This framework, illustrated in Figure 6, views ill health as the product of interactions between physiological risk factors, behavioural risk factors, psychosocial risk factors, and risk conditions. Physiological risk factors include conditions conducive to illness, such as hypertension and hypercholesterolemia, as well as genetic (inherited) factors. Behavioural risk factors refer to the health-damaging actions of individuals, including smoking, poor nutrition, and a sedentary lifestyle. Isolation, lack of social support, a poor social network, low self-esteem, high self-blame, and low perceived power are the psychosocial risk factors identified by the model. Risk conditions are the environmental determinants of health. Poverty, low educational or occupational status,

Figure 6. The Socioenvironmental Approach to Health



**Source:** Toronto, Department of Public Health, "Socioenvironmental Approach to Health," in *Advocacy for Basic Health Prerequisites: Departmental Policy Paper* (Toronto: City of Toronto, 1991).

dangerous or stressful work, dangerous or polluted environments, discrimination (sexism, agism, racism, etc.), low political power, social inequities, lack of access to affordable housing, and inadequate access to food are identified by the model as examples of risk conditions.

The model suggests three approaches to modifying the identified risk factors. The socioenvironmental approach is aimed at psychosocial risk factors and risk conditions. Small group development, community organization, advocacy for healthy public policies, and political action are the primary methods of intervention. The behavioural approach, or reducing multiple risk factors, entails health education, Social Marketing, and advocacy for policies that encourage healthy lifestyle choices as a means of modifying behavioural risk factors. Lastly, the medical or high-risk approach, aimed at altering physiological risk factors, involves surgical intervention, drug therapy, medically managed health behaviour change, and screening.

### **Application of Prevention Target Models**

Although only a few of the prevention target models described in this report have been applied to the modification of risk factors related to infertility, a number of programs promoting healthy birth outcomes have used these approaches.

The increased incidence of reproductive disorders and poor perinatal outcomes among economically disadvantaged groups has been substantiated in a number of studies (Dunn 1984; Shah et al. 1984; Behrman 1985; Kramer 1987). To ensure that expectant mothers have adequate resources, most Western European countries, except for Denmark, pay women a financial bonus during pregnancy (Miller 1987). Sometimes the payment is contingent upon a specified number of prenatal visits.

A project for pregnant adolescents in Norway takes an interesting approach. Single teenaged mothers receive a support package that includes financial assistance. In addition, this initiative provides school-based instruction about sexuality, and media campaigns on contraceptive use. The project has met with considerable success, including decreases in the pregnancy rate (Miller 1987).

### **Current Approaches to Preventing Reproductive Hazards in the Workplace**

A number of preventive strategies premised on individual behaviour models have been implemented to encourage employees to adopt safer practices in the workplace. The Health Belief Model, for example, served as the conceptual basis for a series of television advertisements developed by the Construction Safety Association of Ontario. These messages,



designed to emphasize both the severity of construction accidents and the benefits of taking precautionary measures, were widely recognized by Ontario residents (R. Simpson, personal communication, 18 October 1991).

Social Learning Theory has also been touted as an effective framework for promoting healthy workplaces. Dooner (1990-91) cites the development of self-efficacy as a key strategy for fostering worker health and safety.

In spite of their proven utility in a number of work settings, individual behaviour models should not be considered when designing interventions to prevent exposure to occupational and environmental reproductive hazards. Exhorting workers at risk to perform preventive behaviours, such as wearing protective clothing, may not avert exposure to most reproductive hazards in the workplace. The effects of chemical agents, for example, may not be ameliorated through behaviour modification. Accordingly, using application of individual behaviour models to try to prevent reproductive hazards in the workplace unfairly places responsibility on the employees while overlooking the need to implement structural changes (i.e., reduction or elimination of the hazard).

Preventive approaches derived from group intervention models have also been used in occupational settings. Social Marketing campaigns have become a staple of workplace health and safety programs. In addition to the usual posters and pamphlets, novelty items emblazoned with safety slogans, such as T-shirts and coffee mugs, have been distributed to "sell" workers on the value of precautionary measures (Stratton 1988). As with individual behaviour models, however, Social Marketing does not address those reproductive hazards that cannot be prevented through greater vigilance on the part of the worker.

There have been many instances of workers and communities mobilizing to fight against occupational and environmental hazards. For example, lobbying by community groups in South Riverdale, a densely populated working-class neighbourhood in East Toronto, led to the removal of lead-contaminated soil and the reduction of emissions from a local smelter (Rachlis and Kushner 1989). A similar approach could prove valuable in preventing reproductive hazards in the workplace. Labour unions have mobilized around reproductive health issues in a number of workplaces, but these initiatives are not clearly described in the published literature.

None of the prevention target models described in this report have been specifically applied to the modification or removal of occupational or environmental reproductive hazards. Applying these models to the prevention of reproductive risk factors in the workplace, however, would not be fruitful: the obvious targets for prevention are the hazardous substances themselves.

Preventing exposure to the occupational and environmental risk factors related to infertility entails a three-stage process: identifying the hazard; educating or informing the public about the hazard; and controlling the hazard, which usually involves some form of regulatory measure

(Infante and Tsongas 1983). At present, there is much uncertainty and controversy surrounding each of these.

The surveillance of alleged reproductive hazards in the workplace has been very limited, due in part to a lack of available data (U.S. National Institute for Occupational Safety and Health 1988). There is also a great deal of scientific uncertainty about the effects of exposure to substances thought to have a detrimental impact on reproductive health. As a result, governments and agencies mandated to protect the health of workers are faced with the ethical dilemma of whether to impose preventive regulatory measures against a suspected substance before it has been empirically shown to be a reproductive health risk.

Many public health advocates (see Labonte 1990, for example) have argued that regulatory agencies should be required to confirm the safety of new and existing substances rather than to determine the "absence of harm." While this "guilty until proven innocent" approach may protect workers from exposure to substances that are later found to be hazardous, it may prove to be unwarranted if the substance in question is found to be innocuous at the level of exposure encountered in the workplace. Moreover, when occupational risk factors contributing to infertility do become known, it may not always be possible to eliminate them totally from the worksite.

To resolve the uncertainty surrounding the identification of reproductive hazards in the workplace, the U.S. National Institute for Occupational Safety and Health (1988) recommends the establishment of guidelines for the routine testing of potential reproductive and developmental toxicants, as well as guidelines for assessing and interpreting the data garnered from these testing procedures. In addition, the Institute suggests that detailed epidemiological investigations should be conducted on substances for which a comprehensive literature search found "limited but indicative" or "inadequate" data to classify them as human reproductive toxicants.

Providing employees with information about the hazardous materials in their workplace is mandated by "right to know" legislation in many industrialized countries. In Canada, the Workplace Hazardous Material Information System (WHMIS) was established. WHMIS provides information about workplace hazards in the form of material safety data sheets (MSDS) and warning labels, along with the necessary training in the interpretation and use of this information (Yassi et al. 1989).

As WHMIS has been in operation for only a short period of time (since 31 October 1988), extensive evaluations of its effectiveness in increasing employees' awareness of, and reducing employees' exposure to, hazardous substances in the workplace have yet to be conducted. There is some concern that the training component of WHMIS has not sufficiently familiarized workers with the system (J. Purdham, personal communication, 22 November 1991).

The U.S. National Institute for Occupational Safety and Health (1988) advocates a comprehensive program to educate workers and management about occupational reproductive hazards. Training materials should be specific for exposures found in a given workplace, but should also inform employees about the major personal risk factors (e.g., STDs). Educational programs should help the worker put both occupational and non-occupational risk factors into perspective, so that the relative importance of each can be judged. The establishment of a clearinghouse to collect and disseminate information on reproductive hazards is recommended by the Department as a means of enhancing the educational effort.

The primary regulatory approach to preventing exposure to workplace hazards affecting fertility is to ensure that women are not employed where these identified hazards exist (Hunt 1979). Some employers prohibit women of childbearing age from performing certain jobs considered to be hazardous. This practice is widely employed in the United States, where it is commonly known as medical removal protection (MRP): typically, employees who are particularly susceptible to a hazardous exposure within a particular work area are reassigned to another area in the workplace where the hazard is not present (Ashford 1983).

A variant of this policy is legislated in the province of Quebec. This legislation ensures that pregnant women whose current workplace environment poses a health risk to themselves or to the fetus have a right to change jobs or to take a paid leave for the duration of the risk period (Commission de la santé et de la sécurité du travail du Québec 1984).

In recent years, MRP has come under attack by critics who condemn the practice as a form of gender discrimination (Michel 1990). Efforts to prohibit MRP have been hampered by a recent U.S. court ruling that the exclusion of fertile or pregnant women from certain occupations due to the existence of reproductive hazards in the workplace is permissible if scientifically justified and if less discriminatory alternatives do not exist (*International Union, United Automobile* 1990). Opponents of MRP also contend that reassignment is a "band-aid" solution, providing employers with a cheaper alternative to reducing or eliminating hazardous exposures (Michel 1990). As was previously noted, however, the removal of reproductive toxicants is not always possible.

Regardless of the relative merits and drawbacks of MRP, the need for a more comprehensive approach to preventing exposure to reproductive hazards in the workplace is clear. As part of its plan for preventing reproductive disorders, the U.S. National Institute for Occupational Safety and Health calls for "more active and aggressive development of control systems by major employers" (1988, 24). Given the current fiscal climate, however, it is unlikely that initiatives of this nature will be adopted by many organizations.

Paid mandatory leave (at 34 weeks gestation) is a key component of a comprehensive pre-term birth policy in France (Papiernik et al. 1985). Leave is provided for pregnant women performing jobs requiring continuous



standing, more than 90 minutes of commuting, more than 40 hours of continuous work per week, or hard physical labour.

## **Integrating Approaches: A Proposed Model for Reducing the Incidence of Infertility**

The review of the aforementioned literature led to the following conclusions about the applicability of each of the models reviewed to preventing infertility-related risk factors.

### **Individual Behaviour Models**

As was previously noted, perceived barriers (the cost of performing a preventive health behaviour) is the Health Belief Model component that most accurately predicts and accounts for health-related actions. This element should be incorporated into a framework for the prevention of infertility to account for the personal (e.g., lack of social support) and environmental (e.g., low income) impediments to the cessation of high-risk behaviours and the adoption of preventive practices.

Components of the Theory of Reasoned Action should not be included in a framework to prevent infertility. Behavioural intentions tend to be very unstable over time, and the relationship between behavioural intentions and the actual performance of behaviour over time is weak.

Self-efficacy, the belief that one can perform a particular action, is the Social Learning Theory construct that most accurately accounts for health-related behaviours. Attempts to foster self-efficacy have yielded very positive results in efforts to modify risk factors related to infertility. Accordingly, self-efficacy should be part of a framework to reduce the incidence of reproductive disorders.

### **Group Intervention Models**

Only a few studies using the PRECEDE Model for the prevention of infertility-related risk factors were found. However, the articles that were reviewed indicate that it is a highly effective approach to prevention and health promotion. As was noted, the PRECEDE Model is not restricted to fostering the adoption of new behaviours; it is also concerned with maintaining behaviour over time. Moreover, its components (i.e., predisposing, reinforcing, and enabling factors) are closely related to the elements of the individual behaviour models identified as relevant to the prevention of infertility. Therefore, the major elements of the PRECEDE Model should be incorporated into the framework for the prevention of infertility.

Social Marketing, one of the most widely used approaches to health promotion, does not appear to alter existing attitudes and behaviours



significantly *unless* it is used in conjunction with other methods (e.g., interpersonal instruction). In spite of its questionable merits for changing behaviour, Social Marketing remains a valuable means of raising public awareness and disseminating information about health-related issues.

Diffusion of Innovations Theory, like Social Marketing, has not proven to be particularly effective when applied on its own, especially for encouraging contraceptive use. Accordingly, this approach is inappropriate for the prevention of infertility.

Community organization methods have generally proven to be useful for modifying the risk conditions related to infertility, although it is exceedingly difficult — if not impossible — to determine the extent to which such positive results are attributable to the community mobilization process itself. Nevertheless, outlets for public involvement are essential components of a framework to prevent infertility, given the extent to which environmental factors affect this condition.

## **Prevention Target Models**

The prevention target models are useful for identifying the need to address health factors that are often overlooked. The factors mentioned in the Socioenvironmental Approach to Health are especially relevant to the prevention of infertility.

## **Preventing Infertility in the Workplace or Community**

The prevention of infertility in occupational or community settings necessitates regulatory measures, such as “right to know” legislation, provisions to protect employees or residents at risk (e.g., protective reassignment), and, where possible, the removal of the hazardous agent. Public education, employee or community organization, and preventive services are other approaches that should be considered.

## **Proposed Model**

A comprehensive framework for the prevention of infertility, premised on components of the PRECEDE Model, the Health Belief Model, Social Learning Theory, Social Marketing, community organization methods, and the Socioenvironmental Approach to Health, is depicted in Figure 7.

Like the PRECEDE framework, the model is meant to be read from right to left, so that the planning process begins with the desired outcome in mind. As Green et al. (1980) note, this encourages the asking of *why* questions before the asking of *how* questions: one begins with the result and asks what precedes the result by examining its causes.

The desired outcome is expressed in the model as the reduced incidence of infertility. For the purposes of this report, the reduced incidence of infertility entails the following: an increase in the number of women or couples able to conceive when pregnancy is desired, and an

increase in the number of women able to experience a normal pregnancy and delivery free from infections or exposures that could injure the mother or the developing fetus.

To accomplish this objective, preventive interventions should address both the behavioural and environmental determinants of infertility. Behavioural determinants refer to the high-risk or preventive actions performed by individuals. The model identifies the primary behavioural determinants of infertility as smoking and substance use; sexual behaviour and contraceptive use; weight, diet, and exercise; social interaction; and family planning activities.

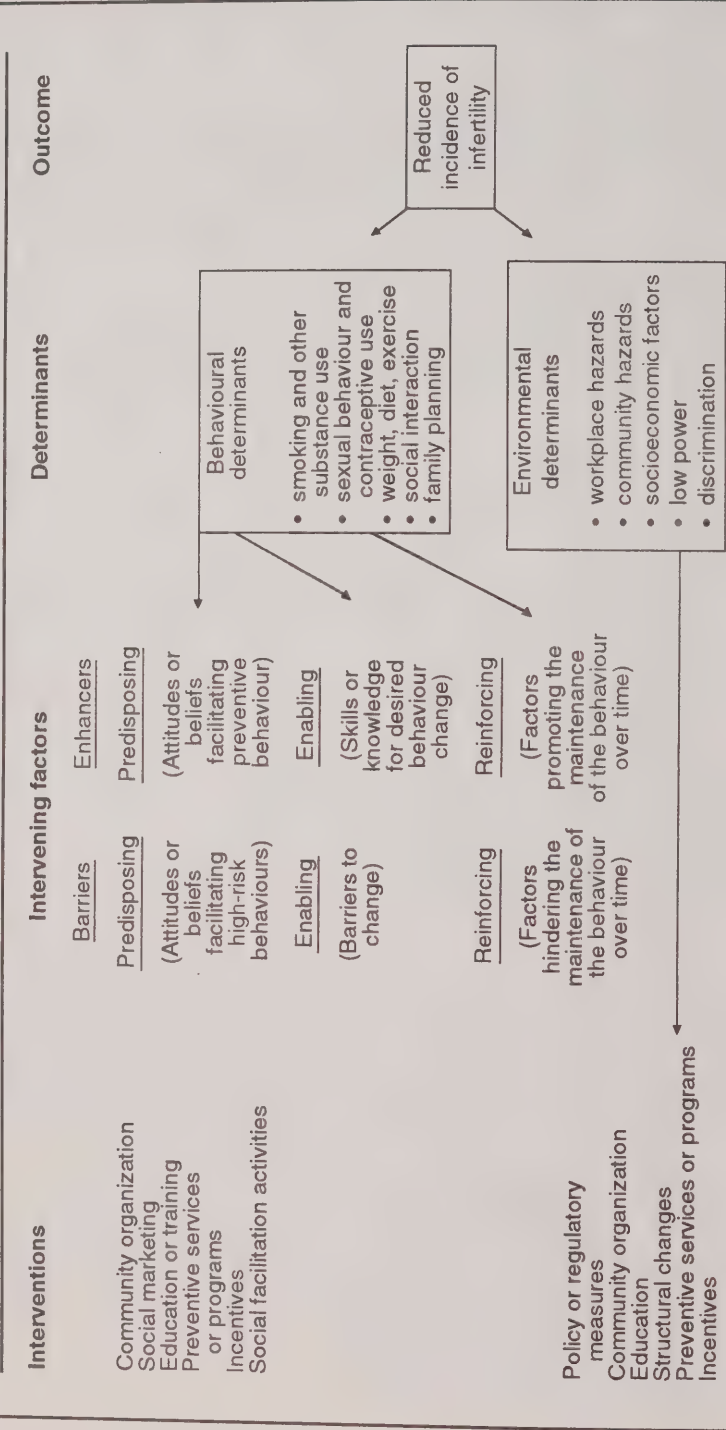
Environmental determinants are the external factors related to infertility. Workplace hazards, community hazards, socioeconomic factors, limited power, and discrimination are the key environmental determinants of infertility.

Before developing interventions to encourage (e.g., safe sex practices) or prevent (e.g., smoking cessation) the behavioural determinants of infertility, the factors enhancing or prohibiting the behaviours should be carefully considered. The model identifies three classes of enhancers and an equal number of barriers. Predisposing enhancers are the personal attitudes or beliefs that facilitate preventive behaviour (e.g., "I will not gain weight as a result of quitting smoking"). Self-efficacy, the most powerful component of Social Learning Theory, is explicitly identified by the model as one of the primary predisposing factors that interventions should try to enhance. Enabling enhancers are the skills or knowledge required for a preventive behaviour to occur (e.g., learning how to use condoms properly). Reinforcing enhancers promote the maintenance of the behaviour over time. Social support for healthy behaviour choices is a prime example of a reinforcing factor. Any approaches to preventing infertility aimed at modifying its behavioural determinants should promote all three classes of enhancing factors.

Similarly, these approaches should also try to eliminate the barriers to infertility-preventing behaviours. Predisposing barriers refer to the attitudes or beliefs that prompt high-risk behaviour (e.g., "Having sex won't be as exciting if I wear a condom"). Enabling barriers are the interpersonal or environmental factors hindering the acquisition of the knowledge and skills needed for successful behaviour change. Interpersonal or environmental factors impeding sustained behavioural change, such as a lack of income to purchase healthy foods, are reinforcing barriers.

The model identifies the following preventive methods as appropriate for addressing the enhancers and barriers to behavioural change: community organization, Social Marketing, education and training, preventive programs and services (e.g., dispensing condoms), incentives for adopting preventive actions, and social facilitation activities (i.e., enhancing social support for behaviour change).

Figure 7. Centre for Health Promotion Model for the Prevention of Infertility



Interventions aimed at modifying the environmental determinants of infertility can be implemented without considering intervening factors. The model suggests the following approaches to preventing these factors: policy or regulatory measures, community organization, public education, structural changes, preventive services and programs (e.g., screening for high-risk occupational groups), and incentives for compliance with preventive measures (e.g., special recognition for “safe” workplaces).

## Recommendations and Relevant Issues

In order to facilitate implementation of the infertility prevention strategy outlined in the model, the adoption of the following measures is suggested.

### Research Priorities

- Make this report available to the key experts and interest groups in the fields of primary prevention and infertility. Feedback about the content of the document and suggestions for addressing the recommendations, as well as the pertinent issues we raised, should be sought from these individuals.
- Develop standard definitions of the various forms of infertility to determine accurately the prevalence of this condition in Canada. Adopting a common terminology will also enable greater understanding of the risk factors linked to infertility and the most appropriate strategies for prevention.
- Promote the establishment of a clearinghouse to collect and collate information on the risk factors related to infertility, to review and identify appropriate strategies of prevention, and to stimulate and coordinate collaborative research and prevention initiatives in the workplace and community.
- Support further studies applying the models described in this report to the prevention of infertility. None of the models have been used to prevent reproductive disorders per se; they have only been applied to modify risk factors related to infertility. Accordingly, a critical appraisal of the models as conceptual frameworks for the prevention of infertility is not possible at present.
- Support further Canadian studies on the applicability of the models considered in this report to the prevention of risk factors related to infertility. At present, there is a paucity of Canadian research in this area. Most of the evidence we examined was American and may not always be relevant to Canadian needs.



## Epidemiology and Surveillance

- Promote the establishment of national, provincial, and regional data systems recording the incidence of reproductive disorders (e.g., spontaneous abortions) in Canada. These systems would identify the segments of the population at greatest risk and monitor the progress in reducing the prevalence of infertility.

## Workplace Prevention of Infertility

- Develop protocols for routine testing and in-depth epidemiological surveys of potential occupational reproductive hazards, as well as guidelines for evaluating and interpreting data derived from this research.
- Identify appropriate preventive counter-measures for all known occupational risk factors linked to infertility. Where appropriate, incorporate this information into user-friendly educational material and training programs. Make this information available to all workplaces where these hazards are present. Monitor the implementation and effectiveness of these strategies.
- Examine the feasibility of a zero-exposure policy in work settings containing confirmed or probable reproductive hazards.
- When zero-exposure is not attainable, implement engineering or administrative controls to maintain hazardous exposures at the lowest levels possible. Examples of administrative controls include job restructuring, task rotation, flexible work hours, and protective reassignment.
- Encourage female employees considering pregnancy to adopt protective counter-measures including early confirmation of pregnancy and early prenatal care.
- Provide smoking cessation sessions and other health promotion programs in the workplace as deemed necessary.

## Community Prevention of Infertility

- Provide resources for communities undertaking demonstration projects to prevent reproductive disorders. These endeavours would foster a greater understanding of the appropriateness of the models discussed in this report for preventing infertility. At present, none of these approaches has been *specifically* applied to the prevention of reproductive disorders; they have only been used to modify risk factors *related* to these outcomes.
- Whenever possible, incorporate infertility prevention strategies into preventive efforts addressing the risk factors related to

reproductive disorders. For example, a STD prevention campaign designed for adolescents could include messages warning that failure to use a condom now could lead to infertility in later life.

- Ensure that all preventive programs and services are culturally appropriate and distributed in an equitable manner.

Lastly, a number of legal, ethical, and economic issues arising from the prevention of infertility are also noted for further consideration:

- Does protective reassignment in the workplace constitute a form of gender discrimination?
- If employees are harmed by exposure to workplace conditions that are subsequently found to be detrimental to reproduction, are they entitled to compensation?
- Establishing a data system for tracking the prevalence of reproductive disorders may entail the collection of personal and confidential information. Who should be granted access to this data system? What provisions should be made to protect the rights of the individual? Does existing federal or provincial legislation apply?
- Should the limited amount of resources available for the prevention of infertility be allocated to the risk factors accounting for the greatest proportion of reproductive disorders, or to the risk factors most amenable to modification?

The entire population is vulnerable to reproductive disorders, regardless of age, gender, ethnicity, sexual orientation, occupation, or socioeconomic status. However, it appears that particular segments of the population, such as blue-collar workers and young people with multiple sex partners, are particularly susceptible to the risk conditions linked to infertility. Under these circumstances, should preventive programs and services be provided to the entire community or to selected high-risk groups? If the latter option is chosen, how can the risk of stereotyping certain segments of the population be avoided?

## Appendix 1. List of Contacts

The following individuals were consulted by the project team over the course of preparing this report. Their advice and contributions are gratefully acknowledged.

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## Appendix 2. Sample Sizes and Composition of Studies Applying Prevention Models to Infertility-Related Risk Factors

<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
<i>Health Belief Model</i>		
Lowe and Radius 1987	283	<ul style="list-style-type: none"> <li>• unmarried college students 18-22 years; mean age: 19 years; predominantly white (6% Black, 6% other ethnic groups)</li> </ul>
Simon and Das 1984	416	<ul style="list-style-type: none"> <li>• American Black and Caribbean Black undergraduate students; mean age: 26.1 years; predominantly low socioeconomic status</li> </ul>
Condelli 1986	632	<ul style="list-style-type: none"> <li>• 13-45-year-old females; mean age: 21.3 years; predominantly white (88.7%), 5% Hispanic</li> </ul>
Petosa and Jackson 1991	679	<ul style="list-style-type: none"> <li>• seventh, ninth, and eleventh grade students; age range: 12-18 years; 33% Black</li> </ul>
Hingson et al. 1990	1 454	<ul style="list-style-type: none"> <li>• adolescents aged 16-19 in Massachusetts; other socio-demographic statistics not specified</li> </ul>
Eisen et al. 1985	120	<ul style="list-style-type: none"> <li>• adolescents in Austin and San Marcos, Texas; 74 females and 46 males; mean age: 14.5 years; 52% Anglo, 22% Black, 23% Hispanic</li> </ul>



<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
Becker et al. 1977	182	<ul style="list-style-type: none"> <li>• low-income mothers (includes some grandmothers); age range: 17-62 years; mean age: 37.2 years; predominantly Black</li> </ul>
O'Connell et al. 1985	169	<ul style="list-style-type: none"> <li>• high school students; 69 obese, 100 non-obese; other socio-demographic characteristics not specified</li> </ul>
Desmond et al. 1990	257	<ul style="list-style-type: none"> <li>• U.S. inner city, low socioeconomic status high school students; 154 Blacks, 93 whites; mean age: 15.9 years</li> </ul>
Biddle and Ashford 1988	901	<ul style="list-style-type: none"> <li>• respondents interviewed in Birmingham and 7 other urban centres in the U.K.; 472 male, 429 female; all over age 16</li> </ul>
Lindsay-Reid and Osborn 1980	124	<ul style="list-style-type: none"> <li>• firefighters in Toronto; all male, aged 24-55 years</li> </ul>
Weissfeld et al. 1990	2 360	<ul style="list-style-type: none"> <li>• adults residing in Michigan; 48% male, 52% female; 91.5% white, 8.5% Black; mixed levels of socioeconomic status</li> </ul>
Weinberger et al. 1981	120	<ul style="list-style-type: none"> <li>• patients receiving care in outpatient department of U.S. teaching hospital; 72% Black, 72% female</li> </ul>
Strecher et al. 1985	213	<ul style="list-style-type: none"> <li>• male inpatients (125) and outpatients (88) at a U.S. Veterans' Administration Medical Centre</li> </ul>

<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
Bardsley and Beckman 1988	407	<ul style="list-style-type: none"> <li>• respondents were in alcoholism treatment program in Los Angeles, or individuals with alcohol problems not receiving treatment; 204 females, 203 males; all respondents were Caucasian, 18 years +</li> </ul>
Beck 1981	272	<ul style="list-style-type: none"> <li>• U.S. college undergraduates; 121 males, 150 females; age range: 17-45; mean age: 20.42 years; predominantly white</li> </ul>
<i>Theory of Reasoned Action or Theory of Planned Behaviour</i>		
Jaccard and Davidson 1972	73	<ul style="list-style-type: none"> <li>• U.S. Caucasian female college students enrolled in an introductory psychology course</li> </ul>
Davidson and Jaccard 1975	270	<ul style="list-style-type: none"> <li>• currently married Caucasian women; sample stratified according to socioeconomic status and religious affiliation (Catholic or Protestant)</li> </ul>
Baker 1988	1 000	<ul style="list-style-type: none"> <li>• patients at STD clinic in U.S.</li> </ul>
Werner and Middlestadt 1979	61	<ul style="list-style-type: none"> <li>• sexually active females enrolled in upper division psychology course at the University of California (Berkeley); other socio-demographic statistics not specified</li> </ul>

<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
McCarty 1981	304	<ul style="list-style-type: none"> <li>students enrolled in Introductory Psychology course in U.S. university; 118 females, 186 males; age range: 16-29 years; 72% aged 16-19 years</li> </ul>
Kar and Talbot 1980	2 447	<ul style="list-style-type: none"> <li>data drawn from cross-cultural surveys of women in Kenya (1 248) and Venezuela (1 199); age range: 18-45 years; Venezuelan women predominantly urban; Kenyan women predominantly rural</li> </ul>
Daltroy and Godin 1989-90	134	<ul style="list-style-type: none"> <li>spouses of cardiac patients in exercise program; other sociodemographic statistics not provided</li> </ul>
Godin 1987	63	<ul style="list-style-type: none"> <li>pregnant women selected from prenatal classes at different centres in Metropolitan Quebec City; mean age: 25.9 years</li> </ul>
Godin and Shephard 1984	698	<ul style="list-style-type: none"> <li>seventh through ninth grade students in North York, Ontario</li> </ul>
Godin et al. 1986	62	<ul style="list-style-type: none"> <li>male, lower-limb disabled adults in the Toronto area</li> </ul>
Godin et al. 1987	136	<ul style="list-style-type: none"> <li>University of Toronto employees; age range: 30-60 years</li> </ul>
Valois et al. 1988	166	<ul style="list-style-type: none"> <li>male (100) and female (66) employees of Laval University; 43% professors, 33% support staff, 24% administrative staff; mean age: 39.7 years</li> </ul>

<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
Pender and Pender 1986	377	<ul style="list-style-type: none"> <li>adult residents of two midwest U.S. communities; 40% male, 60% female; age range: 18-66 years; mean age: 38 years; predominantly white, middle-class</li> </ul>
Tuorila and Pangborn 1988	100	<ul style="list-style-type: none"> <li>U.S. female university students and employees; age range: 16-31 years; mean age: 20.8 years</li> </ul>
Schifter and Ajzen 1985	83	<ul style="list-style-type: none"> <li>U.S. female college students attending undergraduate psychology classes; other socio-demographic statistics not provided</li> </ul>
Roberts 1979	142	<ul style="list-style-type: none"> <li>females enrolled in first-year courses at large midwest U.S. university</li> </ul>
Fishbein 1982		
Marín et al. 1990	413	<ul style="list-style-type: none"> <li>263 Hispanic and 150 Caucasians in San Francisco; approximately equal number of males and females; mean age: 33.3 years; 50% of Caucasians were of low socioeconomic status; 42% of Hispanics were of low socioeconomic status</li> </ul>
Schlegel et al. 1977	196	<ul style="list-style-type: none"> <li>male students at a Catholic high school in Canada; mean age: 15.9 years</li> </ul>



<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
Sheehan et al. 1986	350	<ul style="list-style-type: none"><li>• students attending 3 high schools in Queensland, Australia; schools located in a “middle-class” suburban community, a “depressed” working-class community, and a rural community</li></ul>
<i>Social Learning Theory</i>		
McKinney 1982	179	<ul style="list-style-type: none"><li>• female sophomores attending a U.S. college</li></ul>
Levinson 1982	250	<ul style="list-style-type: none"><li>• females attending a family planning clinic; all respondents 20 years of age or younger</li></ul>
Gilchrist and Schinke 1983	107	<ul style="list-style-type: none"><li>• male and female high school students</li></ul>
Perry et al. 1988	2 250	<ul style="list-style-type: none"><li>• third grade students in Minnesota and North Dakota</li></ul>
Parcel et al. 1989b	473 (approx.)	<ul style="list-style-type: none"><li>• third and fourth grade students attending 4 schools in Texas</li></ul>
Jeffery et al. 1984	89	<ul style="list-style-type: none"><li>• middle-aged men drawn from a randomly selected sample of households in Minneapolis-St. Paul, Minnesota; mean age: 52.8 years</li></ul>
Weinberg et al. 1979	60	<ul style="list-style-type: none"><li>• 30 male and 30 female students attending North Texas State University; age range: 18-23 years</li></ul>

<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
Ewart et al. 1983	40	<ul style="list-style-type: none"> <li>• male patients; mean age: 52 years other sociodemographic statistics not provided</li> </ul>
Sallis et al. 1989	1 789	<ul style="list-style-type: none"> <li>• residents of San Diego, California; most respondents were white, married, college-educated, and relatively affluent</li> </ul>
Hovell et al. 1991	127	<ul style="list-style-type: none"> <li>• Latino residents of San Diego; majority of respondents were male (62%), middle-aged, well-educated, and affluent; mean age: 43.3 years</li> </ul>
Pechacek and Danaheer 1979		
Prochaska and DiClemente 1984	872	<ul style="list-style-type: none"> <li>• male and female community volunteers; mean age: 39 years</li> </ul>
Brod and Hall 1984	108	<ul style="list-style-type: none"> <li>• smokers attending an orientation session for a smoking cessation program; 49 males; 59 females; predominantly single (54%) and middle-to upper-middle class (73%)</li> </ul>
Nicki et al. 1985	49	<ul style="list-style-type: none"> <li>• participants in a smoking cessation program; other sociodemographic statistics not specified</li> </ul>
Pentz 1985	1 193	<ul style="list-style-type: none"> <li>• sixth through ninth grade students from 8 schools in U.S. (4 rural, 4 urban)</li> </ul>

<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
Schinke and Gilchrist 1984	234	<ul style="list-style-type: none"><li>• sixth grade students in the U.S.; other socio-demographic characteristics not specified</li></ul>
Botvin and Eng 1982	426	<ul style="list-style-type: none"><li>• seventh grade students at 2 suburban schools in New York City; 93% white, predominantly middle- to upper-middle class</li></ul>
Botvin et al. 1984	1 185	<ul style="list-style-type: none"><li>• students from 10 suburban junior high schools in New York; predominantly white middle-class</li></ul>
<i>PRECEDE Model</i>		
Mullen et al. 1987	326	<ul style="list-style-type: none"><li>• adults in Denver and Phoenix; age: 17-65 years; 54% female; 56% white; 23% Hispanic; 20% Black; 25% low socioeconomic status; 25% middle to upper socio-economic status</li></ul>
Morisky et al. 1983	400	<ul style="list-style-type: none"><li>• poor, urban patients attending an adult hypertension clinic in Baltimore, Maryland; 70% female; 91% Black; median age: 54 years</li></ul>
Windsor 1986	200	<ul style="list-style-type: none"><li>• women attending 3 maternity clinics in U.S.; 50% married; low socioeconomic status</li></ul>

<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
<i>Diffusion of Innovations Theory</i>		
Berelson and Freedman 1964	36 000 (approx.)	<ul style="list-style-type: none"> <li>• married women in Tai-chung, Taiwan; aged 20-39 years</li> </ul>
Puska et al. 1985	9 241 (1972)	<ul style="list-style-type: none"> <li>• residents of North Karelia county, Finland and comparison site; 3 cross-sectional samples of men and women aged 30-59</li> </ul>
	9 002 (1977)	
	4 273 (1982)	
Mittelmark et al. 1986	500	<ul style="list-style-type: none"> <li>• 25-74-year-old residents of 3 communities in Minnesota and 3 communities in North Dakota surveyed annually</li> </ul>
Nutbeam and Catford 1987	21 940 (approx.)	<ul style="list-style-type: none"> <li>• residents of Wales</li> </ul>
		<ul style="list-style-type: none"> <li>• other sociodemographic statistics not specified</li> </ul>
Parcel et al. 1989b	760	<ul style="list-style-type: none"> <li>• school administrators (483) and teachers (277) at 144 school districts in Texas; teacher characteristics: 51% male; mean age: 40 years; admin. characteristics: 74% male; mean age: 48 years</li> </ul>
Ferrence 1989	n.a.	<ul style="list-style-type: none"> <li>• analyses in study based largely on Canada Health Survey and Labour Force Survey</li> </ul>



<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
<i>Social Marketing</i>		
Hastings and Scott 1987	42	<ul style="list-style-type: none"> <li>residents of Glasgow, Scotland: 14 single males, 7 single females, 7 married female parents of at least one 5-10-year-old child; 7 married female parents of at least one teenager; 7 married male parents; age range of participants: 16-25 years (single respondents); 25-50 years (married respondents)</li> </ul>
Nutbeam et al. 1989	1 303	<ul style="list-style-type: none"> <li>residents of Wales, aged 15-54 years</li> </ul>
Farquhar et al. 1977; Maccoby et al. 1977; Farquhar 1980	2 151	<ul style="list-style-type: none"> <li>random sample of 35-59-year old adults living in 3 California towns; male/female ratio .79; mean age: 47 years; 20% Hispanic</li> </ul>
Ward 1984; U.S. National Center for Health Statistics 1985; Levy and Ward 1979	n.a.	<ul style="list-style-type: none"> <li>results derived from (U.S.) National Heart and Blood Institute surveys conducted between 1973 and 1979</li> </ul>
Green and McAlister 1984	n.a.	<ul style="list-style-type: none"> <li>residents of North Karelia county, Finland</li> </ul>
<i>Community Organization</i>		
Kaseje et al. 1987	229	<ul style="list-style-type: none"> <li>married women in 12 Kenyan villages; aged 15-49 years</li> </ul>

<b>Study</b>	<b>N Size</b>	<b>Sample Composition</b>
Winkelstein et al. 1987	1 034	<ul style="list-style-type: none"> <li>• single men residing in San Francisco neighbourhood with high incidence of HIV; aged 25-55 years</li> </ul>
Ekstrand and Coates 1990	686	<ul style="list-style-type: none"> <li>• gay and bisexual men residing in San Francisco; aged 25-54 years</li> </ul>
Lefebvre et al. 1987	n.a.	<ul style="list-style-type: none"> <li>• residents of Pawtucket, Rhode Island</li> </ul>
Roncarati et al. 1989		
Farquhar et al. 1990	n.a.	<ul style="list-style-type: none"> <li>• 12-74-year-old residents of 4 California cities; 47% male, 83% white; mean age: 36.6 years</li> </ul>
Amezcuca et al. 1990	7 860	<ul style="list-style-type: none"> <li>• residents of Eagle Pass, Texas (6 098 adults, 1 762 young people); predominantly Hispanic; low socioeconomic status</li> </ul>
Pentz et al. 1989	5 008	<ul style="list-style-type: none"> <li>• sixth and seventh grade students attending middle and junior high schools in Kansas; 50% female; 77% white</li> </ul>
Wallerstein and Bernstein 1988	several hundred	<ul style="list-style-type: none"> <li>• Native American high school students in Albuquerque, New Mexico and surrounding area</li> </ul>

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## Mandate

(approved by Her Excellency the Governor General  
on the 25th day of October, 1989)

The Committee of the Privy Council, on the recommendation of the Prime Minister, advise that a Commission do issue under Part I of the Inquiries Act and under the Great Seal of Canada appointing The Royal Commission on New Reproductive Technologies to inquire into and report on current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied, and examining in particular,

- (a) implications of new reproductive technologies for women's reproductive health and well-being;
- (b) the causes, treatment and prevention of male and female infertility;
- (c) reversals of sterilization procedures, artificial insemination, *in vitro* fertilization, embryo transfers, prenatal screening and diagnostic techniques, genetic manipulation and therapeutic interventions to correct genetic anomalies, sex selection techniques, embryo experimentation and fetal tissue transplants;
- (d) social and legal arrangements, such as surrogate childbearing, judicial interventions during gestation and birth, and "ownership" of ova, sperm, embryos and fetal tissue;
- (e) the status and rights of people using or contributing to reproductive services, such as access to procedures, "rights" to parenthood, informed consent, status of gamete donors and confidentiality, and the impact of these services on all concerned parties, particularly the children; and
- (f) the economic ramifications of these technologies, such as the commercial marketing of ova, sperm and embryos, the application of patent law, and the funding of research and procedures including infertility treatment.

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Approaches to the Ethical Issues Raised by the Royal Commission's Mandate	W. Kymlicka
Assisted Reproductive Technologies: Informed Choice	F. Baylis
Medicalization and the New Reproductive Technologies	M. Burgess/A. Frank/ S. Sherwin
Prenatal Diagnosis and Society	D.C. Wertz
Roles for Ethics Committees in Relation to Guidelines for New Reproductive Technologies: A Research Position Paper	J.B. Dossetor/J.L. Storch
Economic, Ethical, and Population Aspects of New Reproductive Technologies in Developing Countries: Implications for Canada	P. Manga

## Volume 2: Social Values and Attitudes Surrounding New Reproductive Technologies

An Overview of Findings in This Volume	RCNRT Staff
Social Values and Attitudes of Canadians Toward New Reproductive Technologies	Decima Research
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Key Findings from a National Survey Conducted by the Angus Reid Group: Infertility, Surrogacy, Fetal Tissue Research, and Reproductive Technologies	M. de Groh



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